NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

April 16-17, 2025

HYATT PLACE
1790 E PLUMB LN
RENO, NV

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

Please do not remove the book from the meeting room.

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

Date Posted: March 26, 2025

FIRST AMENDED AGENDA

◈ PUBLIC NOTICE ◈

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

Hyatt Place
1790 E Plumb Ln
Reno, NV

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

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

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

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

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

   Background Check Not Required by Law.

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

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

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

   F. Catalent Pharma Solutions, LLC – Philadelphia, PA

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

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

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

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

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

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

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

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

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

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

U. Kuehne & Nagel, Inc – Dallas, TX

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

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

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

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

X. AnazaoHealth – Tampa, FL
Y. Oakstead Infusion Vital Care – Layton, UT
Z. Optum Infusion Services 308, LLC – Chandler, AZ
AA. Polomar Specialty Pharmacy, LLC – Palm Harbor, FL
BB. Rush Pharmacy – Oviedo, FL

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

CC. Advanced Diabetes Supply – Carlsbad, CA
DD. AHF Pharmacy – Carson, CA
EE. Aurora Specialty Pharmacy – Menomonee Falls, WI
FF. Get Relief Rx – Billings, MT
GG. Rare Specialty Pharmac – Rahway, NJ
HH. Stellar Rx – Avondale, PA

II. SelectRx KS, LLC – Olathe, KS
JJ. The Art of Medicine – Philadelphia, PA
KK. The Medicine Shoppe – Riverside, CA
LL. US Med, LLC – Miami, FL

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

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

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

◈ REGULAR AGENDA ◈

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

A. Uri Assa Krutilin	(18-052-RPH-S)
B. Eric Math	(19-083-CS-S)
C. McGuff Compounding Pharmacy Services	(23-070-PH-O)
D. McGuff Company, Inc	(23-070-WH-O)
E. Revive Rx	(23-411-PH-O)
F. Injured Workers Pharmacy, LLC	(23-428-PH-O)
G. Meta Pharmacy Services	(24-125-PH-S)
H. Sean Barclay	(24-125-RPH-A-S)
I. Christopher Peters	(24-125-RPH-B-S)
J. Michelle Lyn Badten	(24-125-RPH-C-S)
K. Abdollah Assad	(24-470-CS-N)
L. Alyssa Garcia	(25-076-PT-S)
M. Pulmonary Solutions, LLC	(22-357-MP-N)
N. Lincare, Inc	(24-324-MP-N)
O. Heliodoro Magana	(20-070-PR-N)
P. Frank A Shallenberger	(23-515-CS-N)

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

A. High Vibes Medical Supply, LLC – Las Vegas, NV
B. Med Way Medical Inc – Las Vegas, NV

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

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

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

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

   A. Kuehne & Nagel, Inc – McCarran, NV

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

   A. AMG Pharmacy – Las Vegas, NV
   B. First Choice Pharmacy, LLC – Las Vegas, NV
   C. Healthy Choice Pharmacy – Las Vegas, NV
   D. Meta Pharmacy Services – Las Vegas, NV
   E. Renew Care Pharmacy – Las Vegas, NV

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

    A. Wedgewood Pharmacy LLC – Bakersfield, CA

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

    A. Harsha Nagaraja
    B. Rachel Miceli
    C. Devendrakumar Patel

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

    A. Jorge Menjivar
    B. Samantha Perkins
    C. Rebecca Ballinger

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

◈ WORKSHOP ◈

Thursday, April 17, 2025 – 9:00 am

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

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

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

16. Executive Secretary Report:

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

17. Date and Location of Next Scheduled Board Meeting:

June 4-5, 2025 – Las Vegas, NV

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

19. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

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

MINUTES

March 5-6, 2025

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, March 5, 2025, at 9:00 am. The meeting will continue Thursday, March 6, 2025, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Board Members Present:

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

Board Staff Present:

David Wuest	Gregory Zunino	Brett Kandt	Monica Moazez
Darlene Nases	Erin Miller	Dena McClish	Jessette Phaynarikone
Joe Dodge	Darla Zarley	John Castaldo	Leo Basch
Yenh Long	Todd Weiss	Laura Tucker	Ken Scheuber

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

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

DRAFT

2. Public Comment March 5, 2025, 9:06 AM

There was no public comment.

3. Approval of January 15-16, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Jade Jacobo moved to approve the January 15-16, 2025 Board Meeting Minutes.

Second: Krystal Freitas

Action: Passed unanimously.

◈ CONSENT AGENDA ◈

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

1. Approval of the January 15-16, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

2. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

   A. Bioness Medical Inc – Valencia, CA
   B. Critical Nurse Staffing, LLC – Grand Junction, CO
   C. Element Science, Inc – Redwood City, CA
   D. Impact Medical Services, LLC – Blue Springs, MO
   E. Oxygen Concentrator Supplies – West Berlin, NJ
   F. RGH Enterprises, LLC – Piedmont, SC
   G. Right Coast Medical, LLC – Johnson City, TN
   H. Sleep Doctor – Jacksonville Beach, FL

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

DRAFT

Background Check Not Required by Law.

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

I. McKesson Medical-Surgical, Inc – Columbus, OH
J. RGH Enterprises, LLC – Piedmont, SC
K. Stericycle, Inc – Warren, OH

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

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

L. AbbVie Inc – North Chicago, IL
M. AStraZeneca Pharmaceuticals LP – Newark, DE
N. AStraZeneca Pharmaceuticals LP – Shepherdsville, KY
O. HyperBranch Medical Technology, Inc – Durham, NC
P. Janssen Products, LP – Horsham, PA
Q. LNHC, Inc – Durham, NC
R. Solventum US LLC – Irvine, CA

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

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

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

S. ALK-Abello, Inc – Plainville, CT
T. Catalent Greenville, Inc – Greenville, NC
U. Catalent Indiana, LLC – Bloomington, IN
V. Defibtech, LLC – Bradford, CT
W. Defibtech, LLC – Guildford, CT
X. FSI, Inc – LaVergne, TN
Y. Hugel Aesthetics – Newport Beach, CA
Z. Lupin Pharmaceuticals, Inc – Naples, FL
AA. Lupin Pharmaceuticals, Inc – Somerset, NJ
BB. Pierre Fabre Pharmaceuticals, Inc – Parsippany, NJ
CC. Prollenium US Inc – Raleigh, NC
DD. Purdue Pharma L.P. – Standford, CT
EE. Revelation Wholesale – Casselberry, FL
FF. Rising Pharmaceuticals – Decatur, IL
GG. Rising Pharmaceuticals – Decatur, IL
HH. Ventec Life Systems, Inc – Bothell, WA

DRAFT

II. ZimVie US Corp LLC – Palm Beach, FL

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

JJ. Catalent CTS, LLC – Kansas City, MO
KK. Catalent Pharma Solutions, LLC – Philadelphia, PA
LL. J. Knipper and Company, Inc – Memphis, TN

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

MM. Aspen API Inc – Des Plaines, NC
NN. Airgas USA, LLC – Bothell, WA
OO. Fujifilm Irvine Scientific, Inc – Santa Ana, CA

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

PP. Aditus Pharma Ohio, LLC – West Chester, OH
QQ. AIM Rx3PL, LLC – East Brunswick, NJ
RR. Blue Rabbit Veterinary, LLC – Swedesboro, NJ
SS. Midvalley Central Distribution Pharmacy – Murray, UT
TT. Renown Regional Medical Center Pharmacy – Reno, NV

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

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

UU. Dignity Health – St Rose Dominican – Las Vegas, NV
VV. Omega Specialty Pharmacy – Las Vegas, NV

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

WW. Everwell Specialty Pharmacy – Pensacola, FL
XX. Mixlab TX, LLC – Weatherford, TX
YY. OSRX, Inc – Missoula, MT

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

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ZZ. Apostrophe Pharmacy LLC – Gilbert, AZ
AAA. Eagle Pharmacy LLC – Lakeland, FL
BBB. KnippeRx Inc – Charlestown, IN
CCC. Medmetrics Pharmacy – Chandler, AZ
DDD. Mixlab Inc – New York, NY
EEE. Premise Health Wellness Center – Brentwood, TN
FFF. Stoneview Pharmacy – Gilbert, AZ
GGG. Vetsource Home Delivery – Northlake, TX

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

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

HHH. Ellen Ly

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

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

Board discussion ensued.

Board Action:

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

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Krystal Freitas moved to approve the Consent Agenda Item 4TT.

Second: Jade Jacobo

Action: Passed unanimously (Porath recused).

David Wuest commented that Agenda Item 4NN has the incorrect business city, and the city should be Las Vegas, NV.

◈ REGULAR AGENDA ◈

DRAFT

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

D. Yuko Sweatt (22-214-CS-S)

Joshua Dickey appeared as counsel on behalf of Yuko Sweatt.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Sweatt failed to secure dangerous drugs in a locked cabinet thereby allowing access to dangerous drugs by unlicensed personnel and administered drug products to a patient that were not acquired in compliance with Nevada Law.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 22-214-CS-S for the Board's consideration.

The proposed stipulated penalties for Yuko Sweatt, Certificate of Registration No. CS28545, are the following: 1) public reprimand; 2) Respondent fined $5,000; and 3) Respondent assessed $1,000 in attorney fees and costs. The fine and attorney's fees and costs are due and payable by June 1, 2025.

Board discussion ensued.

Board Action:

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

Second: Jade Jacobo

Action: Passed unanimously.

U. Orthopedic Motion, Inc (24-281-MP-S)
V. Orthopedic Motion, Inc (24-334-MP-S)

David Barney appeared as counsel for Orthopedic Motion, Inc.

Brittany Stryker, representative for Orthopedic Motion, Inc., was present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Orthopedic Motion, Inc. billed insurers for products that were never delivered to patients, failed to maintain an adequate system to resolve complaints by these patients, and failed to notify the Board of the departure of its facility administrator within three business days.

Board discussion ensued.

DRAFT

The proposed stipulated penalties for Orthopedic Motion, Inc. License Nos. MP00772 and MP00026 are the following: 1) Respondents licenses were forfeited as they were not renewed and Respondent would not be eligible to apply for a license or engage in business as a medical products provider or medical products wholesaler for a period of two (2) years after the effective date of this Stipulation; 2) public reprimand; 3) Respondent shall refund payments or deposits as described in sections 1a, 1b, 1c, 1d, and 1f of the Investigate Report in Case No. 24-334-MP-S by June 30, 2025; 4) Respondent fined $5,000; and 5) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Orthopedic Motion Inc. as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

O. Walgreens Pharmacy #07032 (24-083-PH-S)
P. Jennifer Englehaupt (24-083-RPH-A-S)
Q. Cathy Quach (24-083-RPH-B-S)

Bill Stilling appeared as counsel on behalf of Walgreens Pharmacy #07032.

Jennifer Englehaupt and Cathy Quach were present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that as the pharmacy/pharmacy owner, Walgreen's Pharmacy #07032, was responsible for the acts of its employees, Dr. Englehaupt and Dr. Quach, who made an error in a prescription and failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.

The proposed stipulated penalties for Walgreens Pharmacy #07032, License No. PH01747 are: 1) Respondent fined $2,000 due and payable by May 1, 2025; and 2) Respondent assessed $500 in attorney's fees and costs due and payable by May 1, 2025.

The proposed stipulated penalties for Jennifer Englehaupt, Certificate of Registration No. 15287 are: 1) Respondent fined $500 due and payable by May 1, 2025; and 2) Respondent assessed $500 in attorney's fees and costs due and payable by May 1, 2025.

DRAFT

The proposed stipulated penalties for Cathy Quach, Certificate of Registration No. 16344 are: 1) Respondent fined $1,000 due and payable by May 1, 2025; and 2) Respondent assessed $500 in attorney's fees and costs due and payable by May 1, 2025.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Walgreens Pharmacy #07032 as presented by Mr. Zunino.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Cathy Quach as presented by Mr. Zunino.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Jennifer Englehaupt as presented by Mr. Zunino.

Second: Krystal Freitas

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

Action: Motion passed.

S. Walgreens Pharmacy #03845 (24-228-PH-S)

Bill Stilling appeared as counsel on behalf of Walgreens Pharmacy #03845.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Walgreen's Pharmacy #03845 is responsible for the acts of an employee who accessed protected health information for the purpose of learning personal information about a patient.

DRAFT

The proposed stipulated penalties for Walgreens Pharmacy #03845 License No. PH01064 are: 1) Respondent fined $1,000; and (2) Respondent assessed $500 in attorney fees and costs.

Melissa Shake, Health Care Supervisor for Walgreens, was called to testify by Mr. Stilling.

The Board heard testimony and received evidence.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Walgreens Pharmacy #03845 as presented by Mr. Zunino.

Second: Adam Porath

Action: Passed unanimously.

T. Michael Joseph Rhode (24-228-PTT-S)

Michael Rhode failed to appear.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Michael Rhode accessed protected health information for the purpose of learning personal information about a patient.

Darlene Nases, Board Coordinator, was present and called to testify by Mr. Zunino.

The Board heard testimony and received evidence.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that Michael Rhode was properly served with notice of the hearing.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

DRAFT

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 4-11 of the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 12-21 of the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Respondent Rhode guilty on Count One and Count Two, consistent with paragraphs 22-33 of the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo made a motion to retroactively revoke Michael Rhode's Certificate of Registration No. PT28786 to the date of October 31, 2024, the date on which he allowed it to lapse.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award attorney's fees and costs in the amount of $500 on the basis that they were reasonable, necessary, and actually incurred.

Second: Adam Porath

DRAFT

Action: Passed unanimously.

X. Safe Chain Solutions (24-356-WH-O)

Bill Stilling appeared as counsel on behalf of Safe Chain Solutions.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Safe Chain Solutions engaged in the sale and or distribution of counterfeit HIV-1 drugs and transmitted falsified transaction records

Mr. Kandt requested that Exhibit A be entered into the record.

President Park admitted Exhibit A into the record.

Mr. Kandt requested that Exhibits B-D be entered into the record.

Mr. Stilling objected to Exhibits B-D being entered into the record on the basis that they are not relevant.

President Park admitted Exhibits B-D into the record.

Mr. Kandt requested that Exhibit E be entered into the record.

President Park admitted Exhibit E into the record.

Mr. Kandt requested that Exhibit F be entered into the record.

President Park admitted Exhibit F into the record.

Mr. Stilling requested that Exhibits 1-6 be entered into the record.

President Park admitted Exhibits 1-6 into the record.

Mr. Stilling moved to dismiss all claims on the basis of hearsay.

President Park denied Mr. Stilling's motion to dismiss.

Mr. Stilling called Amanda Biggart Chief Operating Officer for Safe Chain Solutions, as a witness. Ms. Biggart was sworn and subject to examination.

Mr. Stilling called Dakota Flowers Compliance Manager for Safe Chain Solutions as a witness. Ms. Flowers was sworn and subject to examination..

The Board received evidence and heard testimony.

Board discussion ensued.

DRAFT

Board Action:

Motion: Jade Jacobo moved to find the Respondent guilty of Count One but with an amendment to remove the statement “into Nevada” from paragraph 14 of the accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to dismiss Count Two and Count Four from the accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Respondent guilty of Count Three of the accusation.

Second: Helen Park

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

Action: Motion passed.

Board Action:

Motion: Jade Jacobo moved to find the Respondent guilty of Count Five and Count Six.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 1, 3, 4, and 5 of accusation.

DRAFT

Second: Richard Tomasso

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraph 2 of the accusation amending the paragraph to solely read as, “Respondent sold and/or distributed counterfeit drugs purportedly manufactured by Gilead Sciences, Inc. (Gilead), for the treatment of HIV-1 patients, including Biktarvy and Descovy“.

Second: Adam Porath

Action: Passed unanimously.

Mr. Kandt requested that the memorandum of attorney’s fees and costs be entered into the record as Exhibit G.

President Park admitted Exhibit G into the record.

Board Action:

Motion: Adam Porath moved to revoke Safe Chain Solutions Wholesaler License No. WH02131 effective immediately. The revocation is stayed, and the Respondent is placed on probation for a period of three (3) years. The Respondent would be required to complete a Board inspection at the owner’s expense.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award the attorney’s fees and costs of $3,584.10 due for payment within 60 days from the effective date of the order on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

DRAFT

Motion: Helen Park moved to approve a $5,000 fine for Safe Chain Solutions due for payment within 60 days from the effective date of the order.

Second: Adam Porath

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

Action: Motion passed.

W. Erin Calderon (24-376-PT-S)

Jade Jacobo disclosed that she was familiar with Erin Calderon due to her time working at CVS Pharmacy but can participate in this matter fairly and without bias.

Erin Calderon was present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Ms. Calderon diverted controlled substances from her place of employment at CVS Pharmacy #8807.

Mr. Zunino requested that pages 2979-2984 of Board Book be entered into the record as Exhibit 1.

President Park admitted Exhibit 1 into the record.

The Board received evidence and heard testimony from Ms. Calderon.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to revoke Erin Calderon's Certificate of Registration No. PT18610 for a period of one (1) year at which time she will need to reappear before the Board if she wishes to petition for reinstatement.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 3-10 of the accusation.

Second: Adam Porath

DRAFT

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 11-14 of the accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find the Respondent guilty on Count One, Count Two, and Count Three consistent with paragraphs 15-20 of the accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Adam Porath moved to not seek attorney's fees and costs in the case against Erin Calderon.

Second: Richard Tomasso

Action: Passed unanimously.

E. Jon Siems (23-449-CS-S and 24-390-CS-S)

Jon Siems was present.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Siems failed to disclose disciplinary order on his 2022 biennial renewal application for his Certificate of Registration No. CS09874. Respondent Siems issued sixty-eight controlled substance prescriptions on a suspended registration and permitted his medical assistants to forge and issue prescriptions for controlled substances.

Mr. Kandt requested that a prescriber activity report and an emailed statement that Dr. Siems provided to the DEA be entered into the record as Exhibit A and Exhibit B, respectively.

DRAFT

Dr. Siems had no objection.

President Park entered Exhibit A and Exhibit B into the record.

The Board received evidence and heard testimony.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 1-11 of the second amended accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 12-25 of the second amended accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Jon Siems guilty on all counts of the second amended accusation.

Second: Adam Porath

Action: Passed unanimously.

Mr. Kandt requested the memorandum of attorney's fees and costs be entered into the record.

Dr. Siems gave no objection to the memorandum of attorney's fees and costs being admitted into the record.

President Park entered the memorandum of attorney's fees and costs into the record as Exhibit C.

Board Action:

DRAFT

Motion: Jade Jacobo moved to revoke Jon Siems Certificate of Registration No. CS09874, effective immediately. Respondent Siems cannot petition for reinstatement for a period of two (2) years.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to impose a $5,000 fine due and payable by June 1, 2025.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award the attorney's fees and costs of $2,968.64 due and payable by June 1, 2025, on the basis that they were reasonable, necessary, and actually incurred.

Second: Adam Porath

Action: Passed unanimously.

C. Rosalina Ross (20-075-PT-S)

Rosalina Ross failed to appear.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent worked as a pharmaceutical technician in training without obtaining a certificate of registration from the Board for the work location.

Jade Jacobo was excused from the meeting at 4:40PM.

Mr. Kandt called Jessette Phaynarikone as a witness.

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

Jade Jacobo returned to the meeting at 4:45PM.

DRAFT

Mr. Kandt requested that the proof of service of the Notice of Intended Action and Accusation together with the Statement to Respondent and Notice of Hearing upon Respondent Ross be admitted into record as Exhibit 1.

President Park admitted Exhibit 1 into the record.

Mr. Kandt requested that the proof of service of a second notice of hearing to Respondent Ross be admitted into record as Exhibit 2.

President Park admitted Exhibit 2 into the record.

Mr. Kandt requested that the courtesy notice via email that he sent to Respondent Ross be entered into the record as Exhibit 3.

President Park admitted Exhibit 3 into the record.

Mr. Kandt called Ken Scheuber as a witness.

Ken Scheuber Board Investigator, was sworn in and subject to examination.

Mr. Kandt requested that the written statement from Ms. Ross to Mr. Scheuber be admitted into the record as Exhibit 4.

President Park admitted Exhibit 4 into the record.

Mr. Kandt requested that the written statement from Sean Barclay, Owner of Meta Pharmacy Services, be admitted into the record as Exhibit 5.

President Park admitted Exhibit 5 into the record.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 1-3 of the accusation and find that the Respondent Ross was properly noticed of the hearing.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make the Conclusions of Law consistent with paragraphs 4-9 of accusation, and to find the Respondent Ross guilty on Count One and Count Two.

DRAFT

Second: Adam Porath

Action: Passed unanimously.

Mr. Kandt requested that the memorandum of costs and fees be entered into the record as Exhibit 7 but noted a correction to the attorney fees and costs before a total of $1,222.85.

Board Action:

Motion: Jade Jacobo moved to revoke the PT license for Rosalina Ross, effective immediately. Respondent cannot apply for reinstatement for a period of one (1) year; and award the attorney's fees and costs of $1,222.85 due and payable by June 1, 2025, on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

A. Eric Math (19-083-CS-N)

This matter was continued.

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

This matter was continued.

F. Matthew Okeke (19-013-CS-S)

This matter was continued.

G. Avrio Pharmacy (20-198-PH-S)

This matter was continued.

H. Partell Specialty Pharmacy (23-175-PH-S)

This matter was continued.

I. Christopher Peters (23-175-RPH-S)

This matter was continued.

J. Partell Specialty Pharmacy (23-239-PH-S)

This matter was continued.

DRAFT

K. Jeffrey Lang (23-239-RPH-S)

This matter was continued.

L. Partell Specialty Pharmacy (23-429-PH-S)

This matter was continued.

M. Robert Seik (23-429-RPH-A-S)

This matter was continued.

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

This matter was continued.

R. Stuart Berliner (24-161-RPH-S)

This matter was continued.

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

A. Rxeed

This matter was continued.

Public comment March 5, 2025, at 4:58 PM

There was no public comment.

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

Board Members Present:

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

Board Staff Present:

David Wuest	Gregory Zunino	Brett Kandt	Monica Moazez
Darlene Nases	Erin Miller	Dena McClish	Jessette Phaynarikone
Joe Dodge	Darla Zarley	John Castaldo	Leo Basch
Yenh Long	Laura Tucker	Ken Scheuber	

Call to Order and Roll Call – Establishment of Quorum

DRAFT

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

Public comment March 6, 2025, at 9:03 AM

There was no public comment.

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

A. Empowering Management of Georgia – North Las Vegas, NV

Evangeline Bess, Co-Owner and Administrator, was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the MDEG application for Empowering Management of Georgia.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. American Life Pharmacy, LLC – Garden City, MI

Amy Khan, Pharmacist in Charge, was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the pharmacy application for American Life Pharmacy, LLC.

Second: Adam Porath

DRAFT

Action: Passed unanimously.

B. Catalent Pharmacy Services – Philadelphia, PA

Michelle Giovannucci (Pharmacist in Charge) and Robert Ciolek (counsel) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the ownership change for Catalent Pharmacy Services.

Second: Adam Porath

Action: Passed unanimously.

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

A. Andrew Hansen

Andrew Hansen was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmaceutical technician in training registration for Andrew Hansen, with the conditions that he receives an initial evaluation and enroll in a PRN-PRN or equivalent program for a period of five (5) years. While enrolled in the program he must have monthly drug tests performed for a period of one (1) year and if there are no issues with the monthly drug tests, the testing will be reduced to quarterly for the remainder of the five years, and he must be evaluated by the program quarterly and the results must be sent to Board staff.

Second: Krystal Freitas

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

DRAFT

Action: Motion passed.

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

A. Bespoke Pharmaceuticals, LLC – North Las Vegas, NV

President Park disclosed that she is familiar with Eric Sparks from her time at Roseman University but could participate in this matter fairly and without bias.

Eric Sparks (Pharmacist), Riccardo Roscetti (CEO), Petr Viskovatykh (Owner and Manager), and Michael Piraturim (translator for Mr. Viskovatykh) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmacy license for Bespoke Pharmaceuticals, LLC, pending inspection that would include a review of their policies and procedures.

Second: Krystal Freitas

Action: Passed unanimously.

B. Family Primary and Specialty Care Pharmacy – Las Vegas, NV

Daniel Taheri and Joseph Montemorano, Pharmacist in Charge, were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the pharmacy license for Family Primary and Specialty Care Pharmacy.

Second: Adam Porath

Action: Passed unanimously.

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

DRAFT

A. Dana Marks

President Park recused herself from this matter due to her employment.

Adam Porath acted as presiding officer.

Dana Marks was present.

The Board heard testimony from Mr. Marks.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance registration renewal for Dana Marks, with conditions to mirror the PRN-PRN or equivalent conditions set by the Nevada State Board of Medical Examiners.

Second: Jade Jacobo

Action: Passed unanimously (Park recused).

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

C. Precision Specialty Rx – Henderson, NV

President Park disclosed that she was familiar with Michelle Kim from her time at Roseman University but can participate in this matter fairly and without bias.

Trevor Harder (Founder), Chris Davin (Executive Director), Michelle Kim (Pharmacist), Joseph Rothman (Consultant), and Jeff Hertz (Consultant) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmacy license for Precision Specialty Rx.

Second: Krystal Freitas

DRAFT

Action: Passed unanimously.

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

D. Melissa Heemsath

Melissa Heemsath was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the controlled substance license for Melissa Heemsath.

Second: Jade Jacobo

Action: Passed unanimously.

C. Victor Jimenez Bonuel

Victor Jimenez Bonuel was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance license for Victor Jimenez Bonuel for schedules II-V, with the condition of PMP training with Board staff prior to the registration being issued and a follow-up training within a six (6) month period.

Second: Adam Porath

Action: Passed unanimously.

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

B. Nicholas Dipirro

DRAFT

Nicholas Dipirro was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmaceutical technician in training license for Nicholas Dipirro.

Second: Krystal Freitas

Action: Passed unanimously.

Adam Porath was excused from the meeting at 12:45PM.

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

B. Guardian DME LLC – Las Vegas, NV

Gevorg Khachoyan, Owner and Administrator, was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the MDEG application for Guardian DME LLC.

Second: President Park

Action: Passed unanimously.

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

B. Pippa Stewart

Pippa Stewart was present.

The Board heard testimony and had questions on the application.

DRAFT

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance application for Pippa Stewart.

Second: Richard Tomasso

Action: Passed unanimously.

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

    A. Mullan Pharmaceutical Inc – Pasadena, CA – Background Check Not Required

Marineh Malek, Chief Compliance Officer and Designated Representative, was present.

This matter was tabled to a future Board Meeting.

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

    H. Vegas Care Pharmacy – Las Vegas, NV

Richard Nguyen (Managing Pharmacist), Rocio Favela (Co-Owner), and Thalia Sokol (Co-Owner) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada pharmacy application for Vegas Care Pharmacy pending Board staff review of the updated application from Mr. Nguyen and a favorable pre-inspection.

Second: Richard Tomasso

Action: Passed unanimously.

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

DRAFT

A. Mullan Pharmaceutical Inc – Pasadena, CA – Background Check Not Required

Marineh Malek, Chief Compliance Officer and Designated Representative, and Dale Xie, Chief Operating Officer, were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the wholesaler application for Mullan Pharmaceutical Inc.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Great Basin Surgery Center – Reno, NV

Michelle McCarthy (Managing Pharmacist), Amy Dalbol (Director of Nursing) and Susan Andersen (Consultant) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Krystal Freitas disclosed that she works for a partial owner in the company and confirmed with the applicants that she can participate in this in this matter.

Board Action:

Motion: Krystal Freitas moved to approve the ambulatory surgery center application for Great Basin Surgery Center.

Second: Jade Jacobo

Action: Passed unanimously.

16. Executive Secretary Report:

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

DRAFT

17. General Counsel Report.

Gregory Zunino, Senior General Counsel, presented.

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

D. Recon Healthcare Services – Elko, NV
E. Recon Healthcare Services – Minden, NV
F. Recon Healthcare Services – Winnemucca, NV
G. Recon Healthcare Services – Yerington, NV

Carlos Bonilla (Administrator) and Jose Montero (Operations Manager) were present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the pharmacy applications for Recon Healthcare Services in Elko, NV, Minden, NV, Winnemucca, NV, and Yerington, NV.

Second: President Park

Action: Passed unanimously.

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

A. Hao Di Pham

Hao Di Pham was present.

The Board heard testimony and had questions on the application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the request for Hao Di Pham to have two (2) opportunities to retake the Nevada MPJE exam within one (1) year.

DRAFT

Second: Anna Carr

Action: Passed unanimously.

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

    A. John Vennochi

This matter was continued.

18. Date and Location of Next Scheduled Board Meeting:

    April 16-17, 2025 – Reno, NV

19. Public Comment March 6, 2025, at 2:46 PM

David Wuest, Executive Secretary for Nevada Board of Pharmacy.

19. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Clara Care Inc

MDEG Physical Address: 3570 Executive Dr. Ste. 102-D

City: Uniontown State: OH Zip: 44685

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: (216) 264-3699 Website: https://www.clarahealthcare.com

Email: dme@clarahealthcare.com

Name of MDEG Administrator (NAC 639.694): Cheryl Carver

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 7:30a-5:30p	■ Tue: 7:30a-5:30p	■ Wed: 7:30a-5:30p	■ Thurs: 7:30a-5:30p	☐ Fri: Closed
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

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

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

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

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

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): N/A

Corporation Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

Contact Person Name: N/A

Date of SEC Registration: N/A	SEC Registration Number: N/A	Stock Exchange Symbol: N/A

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ohio

Parent Company (if any): N/A

Corporation/Organization Name: Clara Care Inc

Mailing Address: 3570 Executive Dr. Ste. 102-D

City: Uniontown State: OH Zip: 44685

Telephone: (216) 264-3699 Email: dme@clarahealthcare.com

Contact Person Name: Cheryl Carver, VP of Clinical Excellence

Section 7: Partnership

Partnership Name: N/A

Mailing Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email:

Contact Person Name: N/A

Section 8: Sole Owner

Owner's Name: N/A

Business Name: N/A

Business Address: N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Email: N/A

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

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

John Everett Crosland

Print Name of Authorized Person Submitting Application

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

Date 2/3/25

Board Use Only	Date Received: 3/10/25	Amount: $500.00

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Clara Care Inc — MDEG License # (if applicable): N/A (Pending)

Physical Address: 3570 Executive Dr Ste 102-D

City: Uniontown — State: OH — Zip: 44685

Mailing Address (if different from physical address): N/A

City: N/A — State: N/A — Zip: N/A

Telephone: (216) 264-3699 — Website: https://www.clarahealthcare.com

Licensing Company Email: licensing@clarahealthcare.com

Section 2: Personal Information

First: Cheryl — Middle: Ann — Last: Carver

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

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

Mailing Address: [redacted]

City: Uniontown — State: OH — Zip: [redacted]

Telephone: [redacted] — Email: cheryl.carver@clarahealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Field High School		06/85-06/89	
Address	**City**	**State**	**Zip**
2900 State Route 43	Mogadore	OH	44260
Diploma/Degree obtained, if any			
General Curriculum			

School Name		From - To (MM/YY – MM/YY)	
Akron School of Practical Nursing		08/99-08/00	
Address	**City**	**State**	**Zip**
619 Sumner Street	Akron	OH	44311
Diploma/Degree obtained, if any			
LPN Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
08/22 to current		Uniontown	OH	
From - To (MM/YY – MM/YY)		City	State	
5/20-8/22		Kent	OH	
From - To (MM/YY – MM/YY)		City	State	
08/19-08/20		Vacaville	CA	
From - To (MM/YY – MM/YY)		City	State	
07/14-08/19		Kent	OH	
From - To (MM/YY – MM/YY)		City	State	
05/12-07/14		Atwater	OH	
From - To (MM/YY – MM/YY)		City	State	
		S, SEE BELOW)		
From - To (MM/YY – MM/YY)		City	State	
05/02-05/04		Kent	OH	
From - To (MM/YY – MM/YY)		City	State	
09/02-11/11		Atwater	OH	
From - To (MM/YY – MM/YY)		City	State	
06/96-05/02		Akron	OH	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				

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

Business Name			From - To (MM/YY – MM/YY)
Clara Care, Inc.			08/2024 to current
Business Address	**City**	**State**	**Zip**
3570 Executive Dr. 102D	Uniontown	OH	44685
Phone	**Title**	**Number of Employed Hours**	
216-264-3699	Chief Compliance Officer	1000	
Description of Duties			
Ensuring that the organization complies with all federal, state, and local laws and regulations governing durable medical equipment operations. This position involves developing, implementing, and maintaining the compliance program, monitoring adherence to policies, and promoting a culture of ethical conduct and accountability.			

Business Name			From - To (MM/YY – MM/YY)
Clara Care, Inc.			12/23-08/24
Business Address	**City**	**State**	**Zip**
11 Apex Dr. Suite 300A PMB 2052	Marlborough	MA	01752
Phone	**Title**	**Number of Employed Hours**	
201-292-7705	VP of Clinical Excellence	2300	
Description of Duties			
Ensure high-quality, patient-centered care by integrating innovative telehealth solutions with advanced wound care products. This role involves driving clinical education, regulatory compliance, and best practices while collaborating with interdisciplinary teams to optimize care delivery.			

Business Name			From - To (MM/YY – MM/YY)
Wound Care Specialist Nurse			08/00-current
Business Address	**City**	**State**	**Zip**
Almost 25 years to date	Akron	OH	44310
Phone	**Title**	**Number of Employed Hours**	
330-807-5037	Master in Wound Care (MAPWCA)	unlimited	
Description of Duties			
Known as an expert in wound ca re for contributions advancing woun care education including Product knowledge, documentation, global education, and expert content writing. Worked in the hospital, LTCFs, for DME specifically in wound care DME.			

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

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

Continue on next page if additional space is needed.

I, Cheryl Carver, certify that as the MDEG Administrator for

Clara Care Inc,

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

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

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

Cheryl Carver
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/23/25
Date

Board Use Only	Date Received 3/10/25

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Clara Care Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A (NV MDEG Pending, OH Attached)

Physical Address: 3570 Executive Dr. Ste. 102-D

City: Uniontown State: OH Zip: 44865

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: (216) 264-3699 Website: https://www.clarahealthcare.com

Licensing Company Email: licensing@clarahealthcare.com

Section 2: Personal Information

First: Nathan Middle: Blake Last: Snyder

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

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

Mailing Address: [redacted]

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

Telephone: [redacted] mail: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Harvard Westlake Highschool		08/88-06/94	
Address	City	State	Zip
3700 Coldwater Canyon Avenue	Studio City	CA	91604
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
UC. Berkeley		08/94-06/98	
Address	City	State	Zip
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
Bachelor Science			

School Name		From - To (MM/YY – MM/YY)	
University of Pennsylvania		08/03-06/05	
Address	City	State	Zip
3451 Walnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 - Current	[redacted]	Los Angeles	CA	[redacted]
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

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

Business Name			From - To (MM/YY – MM/YY)	
LTD-III			10/24-02/25	
Business Address		**City**	**State**	**Zip**
520 S. Sepulveda Blvd #405		Los Angeles	CA	90049
Phone	**Title**			
424-283-0139	Owner			
Description of Duties				
Pool cleaning and maintenance				

Business Name			From - To (MM/YY – MM/YY)	
Clara Care			08/23-01/25	
Business Address		**City**	**State**	**Zip**
3570 Executive Dr. Ste 102-D		Uniontown	OH	44685
Phone	**Title**			
201-292-7705	Board Chair			
Description of Duties				
Assist CEO with strategy development				

Business Name			From - To (MM/YY – MM/YY)	
Redesign Health			09/21-12/23	
Business Address		**City**	**State**	**Zip**
85 5th Ave 8th Floor		New York	NY	10003
Phone	**Title**			
(212) 548-6566	Venture Chair			
Description of Duties				
Launch health care start up companies				

Business Name			From - To (MM/YY – MM/YY)	
Ovation Fertility			05/15-06/21	
Business Address		**City**	**State**	**Zip**
15821 Ventura Blvd #550		Encino	CA	91436
Phone	**Title**			
(818) 858-1080	CEO			
Description of Duties				
Operated Fertility Services Company				

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

Continue on next page if additional space is needed.

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

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

Nathan Snyder

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/25

Date

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

State of Texas, ss. County of Travis

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

Original Signature

2/25/2025

Date

Subscribed and Sworn to before me this 25 day of Feb. 2025.

Notary Public Signature

BENJAMIN RANDOLPH
Notary ID #133993044
My Commission Expires
October 26, 2026
(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Clara Care Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A (MDEG Pending) OH (Attached)

Physical Address: 3570 Executive Dr. Ste. 102-D

City: Uniontown State: OH Zip: 44865

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: (216) 264-3699 Website: https://www.clarahealthcare.com

Licensing Company Email: licensing@clarahealthcare.com

Section 2: Personal Information

First: John Middle: Everett Last: Crosland

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

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

Mailing Address: [redacted]

City: Boylston State: MA Zip: [redacted]

Telephon: [redacted] Email: everett.crosland@clarahealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Johns Hopkins University, School of Arts and Sciences		01/10-05/13	
Address	City	State	Zip
3400 N. Charles Street	Baltimore	MD	21218
Diploma/Degree obtained, if any			
Master of Science			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland, School of Law		08/08	
Address	City	State	Zip
500 W Baltimore St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
Georgetown University		08/02-05/06	
Address	City	State	Zip
3700 O St NW,	Washington	DC	20057
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Shelby High School		08/98-05/02	
Address	City	State	Zip
230 E Dixon Blvd	Shelby	NC	28152
Diploma/Degree obtained, if any			
High school diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/15-present	[redacted]	Boylston	MA	[redacted]
12/12-9/15	[redacted]	Annapolis	MD	[redacted]
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

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

Business Name			From - To (MM/YY – MM/YY)
Clara Care Inc.			09/23-Present
Business Address	**City**	**State**	**Zip**
3570 Executive Dr Suite 102D	Uniontown	OH	44685
Phone	**Title**		
216-264-3699	CEO		
Description of Duties			
Managing the company			

Business Name			From - To (MM/YY – MM/YY)
Cognito Therapeutics			05/21-09/23
Business Address	**City**	**State**	**Zip**
1218 Massachusetts Ave Suite 200	Cambridge	MA	02138
Phone	**Title**		
(857) 201-5088	Chief Commercial Officer		
Description of Duties			
Managing commercial and marketing team, development, and strategy.			

Business Name			From - To (MM/YY – MM/YY)
AppliedVR			11/18-05/21
Business Address	**City**	**State**	**Zip**
16760 Stagg St	Van Nuys	CA	91406
Phone	**Title**		
(844) 857-0010	Chief Commercial Officer		
Description of Duties			
Managing commercial and marketing team, development, and strategy.			

Business Name			From - To (MM/YY – MM/YY)
Pear Therapeutics			07/17-11/18
Business Address	**City**	**State**	**Zip**
200 State Street	Boston	MA	02109
Phone	**Title**		
617-925-7848	VP Market Access, Reimbursement & Government Affairs		
Description of Duties			
Managing payor relations			

Business Name			From - To (MM/YY – MM/YY)
Sunovion Pharmaceuticals			08/15-07/17
Business Address	**City**	**State**	**Zip**
84 Waterford Dr	Marlborough	MA	01752
Phone	**Title**		
(508) 481-6700	Senior Director, Pricing and Reimbursement Strategy		
Description of Duties			
Managing pricing and payor relations			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Durata Therapeutics		09/14-08/15	
Business Address	**City**	**State**	**Zip**
200 South Wacker Drive	Chicago	IL	60606
Phone	**Title**		
(312) 219-7000	Director, Reimbursement Strategy & Market Access		
Description of Duties			
Managing pricing and payor relations			

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

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

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

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

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

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

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

John Everett Crosland

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/25

Date

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

State of Massachusetts, ss. County of Middlesex

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

Original Signature

2/3/25

Date

Subscribed and Sworn to before me this 3 day of February 2025.

Notary Public Signature

(Seal)

eLicense Ohio
Professional Licensure

License Look Up

12/30/2024 8:40 AM

CLARA CARE INC

License Number	HMEL.12061
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Home Medical Equipment Facility License
License Issue Date	08/27/2024
License Expiration Date	06/30/2026
License Effective Date	08/27/2024
Street Address	3570 Executive Dr Ste 102D
City	Uniontown
State	OH
Zipcode	44685-8712
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
		Active	Tue Aug 27 00:00:00 GMT 2024	

Current date & time: **12/30/2024 8:40 AM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
03/10/2025

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

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

PRODUCER	CONTACT NAME:	
The Baldwin Group Specialty Solutions, LLC 4211 West Boy Scout Blvd, Suite 800 Tampa, Florida, 33607	PHONE (A/C No. Ext): 646-854-1058	FAX (A/C No):
	E-MAIL ADDRESS:coi@foundershield.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Underwriters at Lloyd's of London (CFC)	AA-1122000
INSURED	INSURER B : Underwriters at Lloyd's London (Scale)	AA-1122000
Clara Care, Inc 11 APEX DR STE 300A PMB 2052 Marlborough, Massachusetts, 01752	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY ✓ CLAIMS MADE ☐ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ✓ POLICY ☐ PROJECT ☐ LOC ☐ OTHER	✓	☐	MSN0140245345	02/13/2025	02/13/2026	EACH OCCURRENCE	$1,000,000.00
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$250,000.00
							MED EXP (Any one person)	$5,000.00
							PERSONAL & ADV INJURY	$1,000,000.00
							GENERAL AGGREGATE	$3,000,000.00
							PRODUCTS - COMP/OP AGG	$1,000,000.00
	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY	☐	☐				COMBINED SINGLE LIMIT (Ea accident)	
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	☐ UMBRELLA LIAB ☐ EXCESS LIAB ☐ OCCUR ☐ CLAIMS-MADE	☐	☐				Each occurence	
							Aggregate	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYP ROPRIETOR/PARTNER/EXECUTIV OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	☐				☐ PER STATUTE ☐ OTHER	
							E.L. EACH ACCIDEN	
							E.L. DISEASE - EA EMPLOYEE	
							E.L. DISEASE - POLICY LIMIT	
A	Cyber Liability	☐	☐	MSN0140245345	02/13/2025	02/13/2026	$ 1,000,000 per occ	$1,000,000 in agg
A	Errors & Omissions	☐	☐	MSN0140245345	02/13/2025	02/13/2026	$ 1,000,000 per occ	$3,000,000 in agg
B	Directors & Officers	☐	☐	L18SMLPA2174	02/21/2025	02/21/2026	$ 1,000,000 per occ	$1,000,000 in agg
		☐	☐					

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
The Novitas Solutions is included as an Additional Insured on the above referenced policy where required by written contract.

CERTIFICATE HOLDER

Novitas Solutions (NPEast)
PO Box 3704
Mechanicsburg, PA 17050

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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Clara Care

Everett Crosland <everett.crosland@clarahealthcare.com>

National Provider Identifier

customerservice@npienumerator.com <customerservice@npienumerator.com> Mon, Jul 15, 2024 at 11:40 AM

To: EVERETT.CROSLAND@clarahealthcare.com

Enumeration Date: July 15, 2024

A request for a National Provider Identifier for the following provider was recently submitted to https://nppes.cms.hhs.gov, and you were listed as the contact person. This is to inform you that the request was successfully processed and the following NPI has been assigned:1386481463.

CLARA CARE INC
EIN: =====1067

Practice Location:
3570 Executive Dr Ste 102D
Uniontown, OH 44685-8712

Provider Taxonomies:
Taxonomy: 332B00000X
Details: Durable Medical Equipment & Medical Supplies
This is the Primary Taxonomy.

If you have any questions about this notification you may contact the NPI Enumerator Monday through Friday, 9am to 5pm (Eastern Time)* at:
NPI Enumerator
7125 AMBASSADOR RD STE 100
WINDSOR MILL MD 21244-2751
1-800-465-3203 (NPI Toll-Free)
1-800-692-2326 (NPI TTY for the deaf, hard of hearing, or those with speech difficulties)
customerservice@npienumerator.com

*Holiday hours may vary

You may view or change this provider's NPPES information by logging onto the NPPES website at https://nppes.cms.hhs.gov.

Please note: If you are not the provider, you are required to inform the provider of the information in this e-mail and furnish a copy of this notification to the provider.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CLARA CARE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CLARA CARE, INC." WAS INCORPORATED ON THE FIFTEENTH DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5844995 8300

SR# 20250610124

Authentication: 202970915

Date: 02-19-25

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

Board of Certification/Accreditation

Owings Mills, Maryland

Accredited Facility

Practice limited to DMEPOS supplier categories:
S01

The Board of Certification/Accreditation attests that the Facility named below complies with all requirements for facility accreditation.

Clara Care Inc

3570 EXECUTIVE DR STE 102 D
UNIONTOWN, Ohio 44685

This accreditation is awarded for meeting the professional standards of BOC, together with all the honors, rights, privileges and responsibilities in pursuit of our mission to assure patients, physicians, professional organizations, the public-at-large, and government agencies and representatives of the competence and professionalism of BOC-Accredited Facilities.
In witness whereof, we have affixed the seal of the Board and subscribed our names in acknowledgment.

Matthew Gruskin, MBA, BOCO, BOCPD, CDME, Chief Operating Officer

Judi L. Knott, MA, MBA, President & CEO

S72213
Facility Number

October 31, 2027
Accredited Through

Accredited Since: October 04, 2024

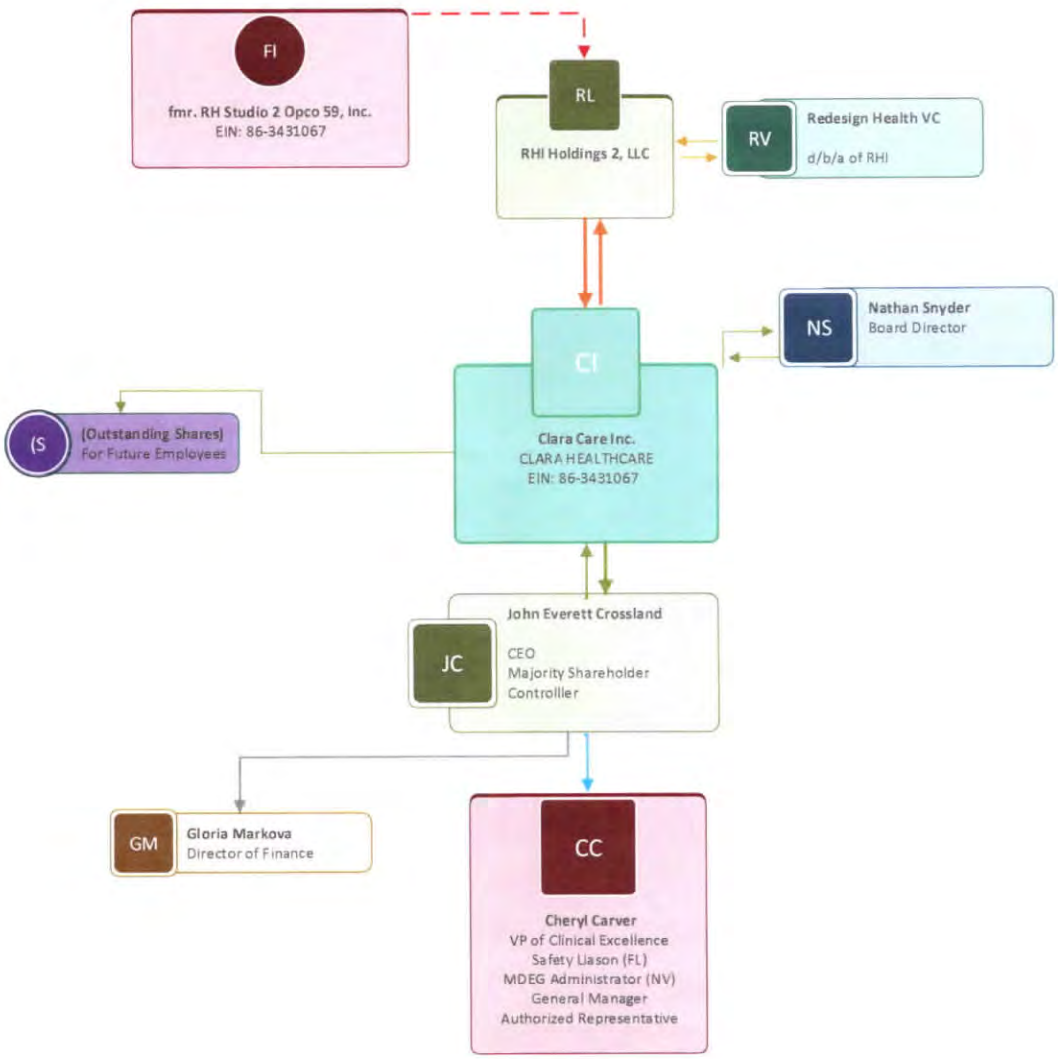
BOC is a CMS deemed accrediting organization.

This accreditation is the property of BOC — the certificate holder agrees to abide by the BOC and CMS standards.

CLARA CARE INC.

Organizational Flow Chart

(Reflects Hierarchy of Ownership and Names of All Owners, Officers, and Directors)



4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Gramatan Health Supplies LLC

MDEG Physical Address: 504 Gramatan Avenue Suite 504

City: Mount Vernon State: NY Zip: 10552-3009

Mailing Address (if different from physical address): 88 Ashford Ave. Suite 103

City: Dobbs Ferry State: NY Zip: 10522-1841

Telephone: 866 786 2624 Website: pending

Email: finance@sun-scientific.com

Name of MDEG Administrator (NAC 639.694): Vikram Ravikumar

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 10 am - 4 pm	■ Tue: 10 am - 4 pm	■ Wed: 10 am - 4 pm	■ Thurs: 10 am - 4 pm	■ Fri: 10 am - 4 pm
☐ Sat: closed	☐ Sun: closed	☐ Holidays: closed		

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Please see attached.

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

Name:	Sundaram Ravikumar	Credentials:	NY Physician 151069	%:	99
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Sun Scientific, Inc.

Corporation/Organization Name: Gramatan Health Supplies LLC

Mailing Address: 88 Ashford Ave. Suite 103

City: Dobbs Ferry State: NY Zip: 10522

Telephone: 866 786 2624 Email: finance@sun-scientific.com

Contact Person Name: Vikram Ravikumar

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Vikram Ravikumar

Print Name of Authorized Person Submitting Application

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

Date 1/15/25

Board Use Only	Date Received:	Amount

Section 3 of Nevada Medical Products Provider Application for Gramtan Health Supplies LLC: Medicaid and Medicare Provider Numbers Registered to the Business

Medicaid or Medicare Provider Number	Issuing State	Issue Date
Provider ID: 127472	Arizona Medicaid	approved 8/3/2023
Provider Number 7101026980	Kentucky Medicaid	approved 1/15/2024 effective 09/01/2024 through 01/31/2026
Provider Number 2649761	Louisiana Medicaid	approved 3/5/2024 effective 12/22/2023
Medicaid number 07663638	New York Medicaid	approved 4/24/24, effective 2/7/2024
1881301018	Texas Medicaid	approved 2/2/2024 effective 10/30/2022
PTAN 8213610001	CMS (Medicare)	approved 4/19/2023 effective 10/30/2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy #206 • Reno • NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

January 31, 2025

To: Gramatan Health Supplies LLC
Att: Vikram Ravikumar
504 Gramatan Avenue Suite 504
Mount Vernon, NY 10552

Enclosed please find your application sent to the Nevada State Board of Pharmacy.
The application is being returned for the following reasons:

NAC 639.6943 Board will not issue license to certain practicing health professionals. (NRS 639.070)

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

(a) A practicing health professional; or

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

2. As used in this section, "practicing health professional" means a health professional who:

(a) Is licensed, certified or registered to practice his or her profession in this State; and

(b) Performs services within the scope of his or her licensure, certification or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

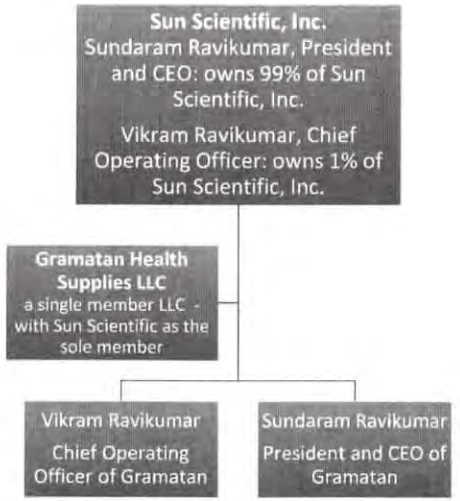
(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R151-05, 11-17-2005; R085-22, 9-28-2022)

Please contact us if you have any questions.

Sincerely,

Nevada State Board of Pharmacy

Gramatan Health Supplies LLC Officers and Ownership Structure



Gramatan
HEALTH SUPPLIES

Gramatan Health Supplies LLC
504 Gramatan Ave. Ste. 100
Mount Vernon, NY 10552-3009

March 3, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

Re: Returned MDEG application

Dear Nevada Pharmacy Board:

We are in receipt of the correspondence dated January 31, 2025 (attached).

We are requesting that the Board take notice that Dr. Sundaram Ravikumar, the only practicing health professional with ownership in Gramatan Health Supplies LLC, is not licensed in the state of Nevada. Dr. Ravikumar's sole medical licensure is with the state of New York, with his license number, 151069, indicated on page 3 of the original application (also attached).

The Code cited in the letter, NAC 639.6943, defines a practicioner as a health professional who "...Is licensed, certified, or registered to practice his or her professon in this State..." We understand "this State" to mean Nevada, where Dr. Ravikumar does not hold a medical license and is not a practicioner.

Based on these points, Gramatan Health Supplies is requesting re-consideration of our original application, attached.

Thank you,

Sincerely,

Vikram Ravikumar, COO
Gramatan Health Supplies LLC

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	GRAMATAN HEALTH SUPPLIES LLC
DOS ID Number:	6595495
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Entity Status:	EXISTING
Date of Initial Filing with DOS:	09/22/2022
Statement Status:	CURRENT
Statement Due Date:	09/30/2026

I certify that the following is a list of documents on file in the Department of State for said entity:

Document Type:	ARTICLES OF ORGANIZATION
Date of Filing:	09/22/2022
Entity Name:	GRAMATAN HEALTH SUPPLIES LLC

Document Type:	CERTIFICATE OF PUBLICATION
Date of Filing:	08/31/2023

Document Type:	CERTIFICATE OF CHANGE BY ENTITY
Date of Filing:	09/06/2023

Document Type:	BIENNIAL STATEMENT
Date of Filing:	09/03/2024

Document Type:	CERTIFICATE OF CHANGE BY ENTITY
Date of Filing:	01/07/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 08, 2025 at 11:28 A.M.

WALTER T. MOSLEY
Secretary of State

BRENDAN C. HUGHES
Executive Deputy Secretary of State

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0079

STATE OF NEW YORK
DEPARTMENT OF STATE
ONE COMMERCE PLAZA
99 WASHINGTON AVENUE
ALBANY, NY 12231-0001
WWW.DOS.NY.GOV

KATHY HOCHUL
GOVERNOR

WALTER T. MOSLEY
SECRETARY OF STATE

Filer: THERESA O'ROURKE NUGENT, ESQ.
LAW OFFICE OF THERESA O'ROURKE NUGENT
520 WHITE PLAINS ROAD, SUITE 500
TARRYTOWN, NY, 10591, USA

Your document has been filed by the Department of State.

We have attached the official filing receipt and related document(s) for the following entity:

DOS ID:	6595495
Entity Name:	GRAMATAN HEALTH SUPPLIES LLC
Statement Due Date:	09/30/2026

- Retain this letter and attachment(s) for your records. The Department of State does not mail additional copies of the filing receipt or related attachment(s).
- Limited Liability Companies are required to file a Biennial Statement with the Department of State. To receive an email notice when the Biennial Statement is due, provide an email address at the Department of State's Email Address Submission/Update Service. https://filing.dos.ny.gov/eBiennialWeb/

Contact Information

- Department of State: Email the Division of Corporations at corporations@dos.ny.gov.
- Department of Taxation and Finance: Visit https://www.tax.ny.gov/help/contact for self-help options and telephone numbers.

NEW YORK STATE OF OPPORTUNITY. | Department of State

NEW YORK STATE DEPARTMENT OF STATE
DIVISION OF CORPORATIONS, STATE RECORDS AND UNIFORM COMMERCIAL CODE

FILING RECEIPT

ENTITY NAME :	GRAMATAN HEALTH SUPPLIES LLC
DOCUMENT TYPE :	CERTIFICATE OF CHANGE BY ENTITY
ENTITY TYPE :	DOMESTIC LIMITED LIABILITY COMPANY
DOS ID :	6595495
FILE DATE :	01/07/2025
FILE NUMBER :	250108001500
TRANSACTION NUMBER :	202501070003729-4046737
EXISTENCE DATE :	09/22/2022
DURATION/DISSOLUTION :	PERPETUAL
COUNTY :	WESTCHESTER

SERVICE OF PROCESS ADDRESS :	THE LLC LEGAL DEPT GRAMATAN HEALTH , 504 GRAMATAN AVE SUITE 100 MOUNT VERNON, NY, 10552, USA
ELECTRONIC SERVICE OF PROCESS EMAIL ADDRESS :	N/A
FILER :	THERESA O'ROURKE NUGENT, ESQ. LAW OFFICE OF THERESA O'ROURKE NUGENT, 520 WHITE PLAINS ROAD, SUITE 500 TARRYTOWN, NY, 10591, USA

You may verify this document online at :	*http://ecorp.dos.ny.gov*
AUTHENTICATION NUMBER :	100007250956

TOTAL FEES:	$80.00	TOTAL PAYMENTS RECEIVED:	$80.00
FILING FEE:	$30.00	CASH:	$0.00
CERTIFICATE OF STATUS:	$25.00	CHECK/MONEY ORDER:	$0.00
CERTIFIED COPY:	$0.00	CREDIT CARD:	$80.00
COPY REQUEST:	$0.00	DRAWDOWN ACCOUNT:	$0.00
EXPEDITED HANDLING:	$25.00	REFUND DUE:	$0.00

Steven LaGreca

From: PHARMBD <PHARMBD@nysed.gov>
Sent: Thursday, August 31, 2023 4:34 PM
To: Steven LaGreca
Subject: RE: licensing question

Dear Steve,

The Pharmacy Board Office does not have purview or oversee durable medical equipment (DME). Please note, registration is not required with the Pharmacy Board Office for DME suppliers.

Sincerely,
Jeffrey Fisher
Administrative Assistant Trainee 2

OFFICE OF THE PROFESSIONS
www.op.nysed.gov

New York State Education Department
Board Office for Pharmacy & Midwifery
89 Washington Ave., 2nd Floor West
Albany, NY 12234
Phone: 518-474-3817 ext. 130
Email: pharmbd@nysed.gov
Web: www.op.nysed.gov

"Please understand that the Education Department does not answer hypothetical questions, issue advisory opinions or offer detailed legal advice. Such requests should be directed to your attorney. While we can share with you commonly accepted interpretations of applicable laws and regulations, it should be noted that the applicability of statutes and regulations depend ultimately on the distinctive nature of a particular case, which will change given a different set of circumstances."

From: Steven LaGreca <Steven@mssprop.com>
Sent: Thursday, August 31, 2023 1:33 PM
To: PHARMBD <PHARMBD@nysed.gov>
Subject: licensing question

Good morning,

A DME Supplier that is located within New York State, would also be retailing the following DMEPOS categories within New York State:

DM08, heat and cold applications
OR02, orthoses, prefabricated (non custom-fabricated)
OR03, orthoses, off-the-shelf
DM18 pneumatic compression devices, including HCPCS codes E0650 pneumatic compressor non-segmental home model and E0673 Segmental gradient pressure pneumatic appliance, half leg.
S01, surgical dressing

Could you please confirm, is any specific New York State license required for the supplier located in New York State, in order to send/sell to consumers (patients) in New York State?

Thank you,

Steve

STEVEN T. LAGRECA, MA, MBA
CLIENT COMPLIANCE INITIATIVE AND STRATEGIES

MSS PROPERTY SOLUTIONS, INC.
1979 MARCUS AVENUE STE. 201
LAKE SUCCESS, NY 11042
516 376 5778

Confidentiality Notice

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SUNSCIE-01 JDICARLO

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 9/12/2024

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

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

PRODUCER
J.A. Faccibene & Assoc., Inc.
100 Merrick Rd
Suite 526W
Rockville Centre, NY 11570

CONTACT NAME:
PHONE (A/C, No, Ext): (516) 766-3513 FAX (A/C, No): (516) 766-3606
E-MAIL ADDRESS: certificates@jafinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Continental Casualty Company	20443
INSURER B : Hartford Accident & Indemnity	22357
INSURER C : Kinsale Insurance Company	38920
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Gramatan Health Supplies LLC
504 Gramatan Avenue, Suite 100
Mount Vernon, NY 10552

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			6021226995	8/25/2024	8/25/2025	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:						PROD LIAB EXCLU	$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 2,000,000
	EXCESS LIAB CLAIMS-MADE			6021227001	8/25/2024	8/25/2025	AGGREGATE	$
	DED X RETENTION $ 10,000						Aggregate	$ 2,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N N / A			12WECAY00PH	5/1/2024	5/1/2025	E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	General Liability			0100268017-0	11/7/2023	11/7/2024	See Remarks	
C	General Liability			0100268017-0	11/7/2023	11/7/2024	See Remarks	

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

CERTIFICATE HOLDER

Proof of Coverage

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Joseph A Faccibene

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NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Gramatan Health Supplies LLC

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

Physical Address: 504 Gramatan Avenue Suite 100

City: Mount Vernon State: NY Zip: 10552

Mailing Address (if different from physical address): 88 Ashford Avenue Suite 103

City: Dobbs Ferry State: NY Zip: 10522

Telephone: 866-786-2624 Website: pending

Licensing Company Email: finance@sun-scientific.com

Section 2: Personal Information

First: Sundaram Middle: Last: Ravikumar

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

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

Mailing Address: [redacted]

City: Briarcliff Manor State: NY Zip: [redacted]

Telephone: [redacted] Email: ravi@sun-scientific.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
NY Medical College			07/83-06/84	
Address		City	State	Zip
40 Sunshine Cottage Road		Valhalla	NY	10595
Diploma/Degree obtained, if any				
Vascular Fellowship				

School Name			From - To (MM/YY – MM/YY)	
NY Medical College			07/81-06/82	
Address		City	State	Zip
40 Sunshine Cottage Road		Valhalla	NY	10595
Diploma/Degree obtained, if any				
Chief Surgical Resident				

School Name			From - To (MM/YY – MM/YY)	
NY Medical College			07/77-06/81	
Address		City	State	Zip
40 Sunshine Cottage Road		Valhalla	NY	10595
Diploma/Degree obtained, if any				
Surgical Residency				

School Name			From - To (MM/YY – MM/YY)	
Safdarjang Hospital/Delhi University			07/76-06/77	
Address		City	State	Zip
14, Sri Aurobindo Marg, New Delhi, Delhi 110029, India				
Diploma/Degree obtained, if any				
Junior Residency Medicine and Junior Residency Surgical				

School Name			From - To (MM/YY – MM/YY	
Armed Forces Medical College			07/70-12/75	
Address		City	State	Zip
Wanowrie, Pune 411040. Maharashtra, India				
Diploma/Degree obtained, if any				
MBBS/Distinction in Ob/Gyn				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/85-present	[redacted]	, Briarcliff Manor	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Gramatan Health Supplies LLC			09/22-present	
Business Address		**City**	**State**	**Zip**
504 Gramatan Ave. Suite 100		Mount Vernon	NY	10552
Phone	**Title**			
566 786 2624	President and CEO			
Description of Duties				
advisory oversight				

Business Name			From - To (MM/YY – MM/YY)	
Sun Scientific, Inc.			03/10-present	
Business Address		**City**	**State**	**Zip**
145 Palisade St. Suite LL-11		Dobbs Ferry	NY	10522
Phone	**Title**			
855 656 5656	Founder/CEO			
Description of Duties				
Invent and develop venous compression and wound care products to treat chronic venous disease and to prevent DVT and pressure/ulcers				

Business Name			From - To (MM/YY – MM/YY)	
New York Medical College			07/82-present	
Business Address		**City**	**State**	**Zip**
40 Sunshine Cottage Road		Valhalla	NY	10595
Phone	**Title**			
(914) 594-4495	Clinical Assistant Professor, Department of Surgery			
Description of Duties				
teaching				

Business Name			From - To (MM/YY – MM/YY)	
Private Practice/Westchester Vascular PLLC			07/82-present	
Business Address		**City**	**State**	**Zip**
88 Ashford Ave		Dobbs Ferry	NY	10522
Phone	**Title**			
(914) 591-8400	Private Practice			
Description of Duties				
Private vascular and general surgery practice with hospital privileges				

Business Name			From - To (MM/YY – MM/YY)	
Lincoln Hospital			07/82-06/83	
Business Address		**City**	**State**	**Zip**
234 E 149th St.		Bronx	NY	10451
Phone	**Title**			
(718) 579-5000	Clinical Assistant Professor, Department of Surgery			
Description of Duties				
teaching				

Continue on next page if additional space is needed.

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

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

Sundaram Ravikumar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/25

Date

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

State of New York, ss. County of Westchester

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

Original Signature

11/15/25

Date

Subscribed and Sworn to before me this 15th day of January 2025

Notary Public Signature

THERESA O'ROURKE NUGENT
Notary Public, State of New York
Reg. No. 02NU6236232
Qualified in Westchester County
Commission Expires July 31, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Gramatan Health Supplies LLC

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

Physical Address: 504 Gramatan Avenue Suite 100

City: Mount Vernon State: NY Zip: 10552

Mailing Address (if different from physical address): 88 Ashford Avenue Suite 103

City: Dobbs Ferry State: NY Zip: 10522

Telephone: 866-786-2624 Website: pending

Licensing Company Email: finance@sun-scientific.com

Section 2: Personal Information

First: Vikram Middle: Last: Ravikumar

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

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

Mailing Address: [redacted]

City: New York State: NY Zip: [redacted]

Telephone: [redacted] Email: vikram@sun-scientific.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Columbia University School of Continuing Education		06/13-07/13	
Address	**City**	**State**	**Zip**
116th and Broadway	New York	NY	10027
Diploma/Degree obtained, if any			
"Intro to Finance" and "Corporate Finance": GPA: 4.0 - Summer 2013			

School Name		From - To (MM/YY – MM/YY)	
Union College		09/05-05/09	
Address	**City**	**State**	**Zip**
807 Union Street	Schenectady	NY	12308
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Briarcliff High School		09/00-06/04	
Address	**City**	**State**	**Zip**
444 Pleasantville Road	Briarcliff Manor	NY	10510
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/15-present	[redacted]	New York	NY	[redacted]
05/86-07/15	[redacted]	Briarcliff Manor	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Gramatan Health Supplies LLC			09/22-present	
Business Address		**City**	**State**	**Zip**
504 Gramatan Avenue Suite 100		Mount Vernon	NY	10552
Phone	**Title**			
866-786-2624	Chief Operating Officer			
Description of Duties				
Oversee all business operations for pneumatic compression, wound care and lymphedema garment DME: sales, reimbursements, finance and accounting, compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Sun Scientific, Inc.			03/20-present	
Business Address		**City**	**State**	**Zip**
145 Palisade St. Suite LL-11		Dobbs Ferry	NY	10522
Phone	**Title**			
855-656-5656	Chief Operating Officer			
Description of Duties				
Work with founder and small R&D team, developing new products and technologies, leading commercialization strategy and execution of IP (50+ patents). Product launches (20+) and gathering feedback/adjusting design/launch strategy.				

Business Name			From - To (MM/YY – MM/YY)	
Sun Scientific, Inc.			12/14-03/20	
Business Address		**City**	**State**	**Zip**
145 Palisade St. Suite LL-11		Dobbs Ferry	NY	10522
Phone	**Title**			
855-656-5656	Vice President			
Description of Duties				
Oversaw business ops: sales, logistics, finance, accounting. Developed strategy for 8 product lines in 3 verticals: R&D, IP, compliance, distribution. Designed Beta Test programs; managed product/patent license.				

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

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

Continue on next page if additional space is needed.

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

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

Ravikumar, Vikram

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/15/25

Date

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

State of New York, ss. County of Westchester

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

Original Signature

1/15/25

Date

Subscribed and Sworn to before me this 15th day of January 2025

Notary Public Signature

THERESA O'ROURKE NUGENT
Notary Public, State of New York
Reg. No. 02NU6236232
Qualified In Westchester County
Commission Expires July 31, 2028

(Seal)

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Gramatan Health Supplies LLC — MDEG License # (if applicable): pending
Physical Address: 504 Gramatan Avenue Suite 100
City: Mount Vernon — State: NY — Zip: 10552
Mailing Address (if different from physical address): 88 Ashford Ave. Suite 103
City: Dobbs Ferry — State: NY — Zip: 10522
Telephone: 866 786 2624 — Website: pending
Licensing Company Email: finance@sun-scientific.com

Section 2: Personal Information

First: Vikram — Middle: — Last: Ravikumar
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted]
City: New York — State: NY — Zip: [redacted]
Telephone: [redacted] — Email: vikram@sun-scientific.com
Are you a citizen of the United States? ☑ Yes ☐ No

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Columbia University School of Continuing Education		06/13-07/13	
Address	**City**	**State**	**Zip**
116th and Broadway	New York	NY	10027
Diploma/Degree obtained, if any			
"Intro to Finance" and "Corporate Finance": GPA: 4.0 - Summer 2013			

School Name		From - To (MM/YY – MM/YY)	
Union College		09/05-05/09	
Address	**City**	**State**	**Zip**
807 Union Street	Schenectady	NY	12308
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Briarcliff High School		09/00-06/04	
Address	**City**	**State**	**Zip**
444 Pleasantville Road	Briarcliff Manor	NY	10510
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	
08/15-present	[redacted]	New York	NY	[redacted]
From - To (MM/YY – MM/YY)		City	State	
05/86-07/15		Briarcliff Manor	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Gramatan Health Supplies LLC			09/22-present	
Business Address		**City**	**State**	**Zip**
504 Gramatan Avenue Suite 100		Mount Vernon	NY	10552
Phone	**Title**		**Number of Employed Hours**	
866-786-2624	Chief Operating Officer,170		4,170	
Description of Duties				
Oversee all business operations for pneumatic compression, wound care and lymphedema garment DME: sales, reimbursements, finance and accounting, compliance.				

Business Name			From - To (MM/YY – MM/YY)	
Sun Scientific, Inc.			03/20-present	
Business Address		**City**	**State**	**Zip**
145 Palisade St. Suite LL-11		Dobbs Ferry	NY	10522
Phone	**Title**		**Number of Employed Hours**	
855-656-5656	Chief Operating Officer		8,130	
Description of Duties				
Work with founder and small R&D team, developing new products and technologies, leading commercialization strategy and execution of IP (50+ patents). Product launches (20+) and gathering feedback/adjusting design/launch strategy.				

Business Name			From - To (MM/YY – MM/YY)	
Sun Scientific, Inc.			12/14-03/20	
Business Address		**City**	**State**	**Zip**
145 Palisade St. Suite LL-11		Dobbs Ferry	NY	10522
Phone	**Title**		**Number of Employed Hours**	
855-656-5656	Vice President		13,167	
Description of Duties				
Oversaw business ops: sales, logistics, finance, accounting. Developed strategy for 8 product lines in 3 verticals: R&D, IP, compliance, distribution. Designed Beta Test programs; managed product/patent license.				

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

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

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

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

I, Vikram Ravikumar, **certify that as the MDEG Administrator for**

Gramatan Health Supplies LLC,

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

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

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

Vikram Ravikumar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/15/25

Date

Board Use Only	Date Received: 11/21/25

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Graymont Equipment Distribution, LLC

MDEG Physical Address: 2214 W Hubbard St

City: Chicago State: IL Zip: 60612-1614

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 312-291-9305 Website: www.graymontmedical.com

Email: compliance@graymontmedical.com

Name of MDEG Administrator (NAC 639.694): Kara Albert

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: See list attached.
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: 312-291-9305

NOTE: GRAYMONT HAS A 24/7 ANSWERING SERVICE.

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 6:30AM-3PM	■ Tue: 6:30AM-3PM	■ Wed: 6:30AM-3PM	■ Thurs: 6:30AM-3PM	■ Fri: 6:30AM-3PM
☐ Sat:	☐ Sun:	■ Holidays: Open most holidays at same business hours		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
7526600001 (MEDICARE PTAN)
371689099001(IL) 0234362(OH)
100305700 (WI)
710073132O(KY)

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

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinois

Parent Company (if any): _____

Corporation/Organization Name: Graymont Equipment Distribution, LLC

Mailing Address: 2214 W Hubbard St

City: Chicago State: IL Zip: 60612

Telephone: 3122919305 Email: Compliance@graymontmedical.com

Contact Person Name: Kara Albert

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

NA

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

Kara Albert

Print Name of Authorized Person Submitting Application

Kara Albert

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

2/10/2025

Date

Board Use Only	Date Received: 2/24/25	Amount: $500-cc

GRAYMONT MEDICAL

Ownership Structure

Nick Wright – Member 20% ✓
[redacted]

Gray Medical Inc – Member 45% - [redacted]
[redacted]

Bryce Beasley – Member 35% ✓
[redacted]

Authorized Officials/ Officers

Bryce Beasley
Chief Executive Officer
[redacted]

Kara Albert
Chief Operating and People Officer
[redacted]

Directors

Kyle Gebhardt
Controller

Mary Mitchell
VP, Strategic Operations

Jennifer Belk
Director of IT

Jay Seymour
Regional Sales Director

Matt Wachter
Regional Sales Director

Jaime Mazur
Director of Revenue Cycle

Sarah Nagengast-Lanning
Associate Director, Operations

Simone Schwartz
Associate Director, Business Operations

Graymont Medical Organizational Chart

Updated:2/17/202

CEO
Bryce Beasley

COO/CPO
Kara Albert

Orthotist
Thaddeus Holgado

Surgical Sales
Jake Richter – Lead
Faye Weldon – Specialist
Kyle Beyak - Specialist

Territory Sales Managers
Alex Jones
Kyleigh (Hamacher) Salter
Roch Leffler
Corbin Scholtes
Jared Weaver

Assoc. Sales Representative
Walter Gamon
Bill Kuta
Madeline Naimo
Max Almaraz
Amaury Rubio

Spine Division
Colin Rowland - Lead
Kevin Malone

DME Sales
Darby Carroll
Jay Seymour (Northeast)
Matt Wachter (Midwest)

VP, Strategic Operations
Mary Mitchell

Information Technology
John Zalewski – Lead
Jen Belk – Director
Heidi Zalewski - Support

Operations
Sarah Nagengast-Lanning – Operations
Simone Schwartz – Business Ops
Annie Fair

Accounting / Finance
Kyle Gebhardt – Controller
Jake Langbehn – Staff Acct
Natalie Park

Patient Care
Rebecca Maldonado - Service Tech Lead
Alexa Oceguera
Sophia Ahmed
Lauren Frugoli
Jenna Ayers

Registration
Abrial Bourge
Claire Chalifoux
Kraig Kelsey
Matt Novotny
Yolanda Pareja
Dane Hanson

Revenue Cycle
Jaime Mazur – Dir
Alex Gomez – Lead
Kelly Wicks – Lead
Gina Medina
Cynara Crespo
Hamda Mirza
Doug Steckel

Service Technician
Steve Portschy
Juan Soto-Alvarado
Kevyauna Sams
Kyle Dubin

Orthotic Fitters
Robbie Byrd
Julian Negrete
Jaybee Navarra
Ruth Monteyro

Warehouse-Inventory
Matt Byrne – Manager
Alec Perez – Manager
Dalton Johnson
Sonja Linton
Mike Castillo - Delivery

GRAYMONT MEDICAL

File Number 0390827-5

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

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

GRAYMONT EQUIPMENT DISTRIBUTION, LLC, HAVING ORGANIZED IN THE STATE OF ILLINOIS ON MARCH 27, 2012, AND HAVING ADOPTED THE ASSUMED NAME OF GRAYMONT MEDICAL ON APRIL 29, 2014, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LIMITED LIABILITY COMPANY IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 31ST *day of* JANUARY *A.D.* 2025 .

Authentication #: 2503102512 verifiable until 01/31/2026

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

SECRETARY OF STATE

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
203.002906

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
03/31/2027

HOME MEDICAL EQUIPMENT AND SERVICES PROVIDER

GRAYMONT EQUIPMENT DISTRIBUTION LLC
KARA ALBERT
2214 W HUBBARD ST
CHICAGO, IL 60612-1614

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

19124749

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 3747289

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/30/2024

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

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

PRODUCER
Marsh & McLennan Agency LLC
20 North Martingale Road
Schaumburg IL 60173

CONTACT NAME: Sockha Chau
PHONE (A/C, No, Ext): (847) 463-7277 **FAX (A/C, No):** (847) 440-9127
E-MAIL ADDRESS: Sockha.Chau@MarshMMA.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Continental Insurance Company	35289
INSURER B : Continental Casualty Co	20443
INSURER C : American Casualty Company of R	20427
INSURER D :	
INSURER E :	
INSURER F :	

INSURED GRAYEQU-01
Graymont Equipment Distribution, LLC
2214 W Hubbard St
Chicago IL 60612

COVERAGES **CERTIFICATE NUMBER:** 1934472110 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	COMMERCIAL GENERAL LIABILITY			6014793309	4/23/2024	4/23/2025	EACH OCCURRENCE	$ 1,000,000
	[ ] CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 15,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	[ ] POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 0
	OTHER:							$
A	AUTOMOBILE LIABILITY			6046396312	4/23/2024	4/23/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	[X] ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	[X] UMBRELLA LIAB [X] OCCUR			6014792676	4/23/2024	4/23/2025	EACH OCCURRENCE	$ 3,000,000
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$ 3,000,000
	[ ] DED [ ] RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						[ ] PER STATUTE [ ] OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
B	Products Liability			ADT6018262461	4/23/2024	4/23/2025	Limit:	5,000,000
							Aggregate:	5,000,000

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

CERTIFICATE HOLDER

* Sample *

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Gina Poljak

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GRAYMONT
MEDICAL

Our DME Products

We make the conscious decision to exist as a vendor-neutral organization so we can ensure that we are stocked with the best equipment and DME for every need.

BRACING & ORTHOTICS

- Contracture treatments devices: Dynamic splints
- Custom Fit Orthotics
- Off-the-shelf Orthotics
- Back to Sports Braces

DURABLE MEDICAL EQUIPMENT & SUPPLIES

- Cold therapy and heat applications
- DVT Units
- Continuous Passive Motion (CPM) devices
- Nebulizers Equipment and/or supplies
- Neuromuscular Electrical Stimulators (NMES) and/or supplies
- Transcutaneous electrical nerve stimulators (TENS) and/or supplies
- Bone Stimulators
- Bathroom Safety
- Canes and/or crutches
- Commodes/Urinals/Bedpans
- Traction Equipment
- Walkers
- Wheelchairs seating/cushions
- Wheelchair (Standard Manual)
- External Pain Pumps
- Virtual Reality- Based Therapies
- Ocular Pressure Adjusting Pump (OPAP) system

Get In Touch

To place a **Home Delivery DME** order:

E: Intake@graymontmedical.com
P: (312) 291-9305
F: (312) 896-1436

To place a **Purchase Order:**

E: Orders@graymontmedical.com
P: (312) 583-7298

Graymont Equipment Distribution, LLC
Graymont Medical

Chicago, IL

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

September 21, 2024

Accreditation is customarily valid for up to 36 months.

Michael Suk, MD, JD, MPH, MBA, FACS
Chair, Board of Commissioners

ID #582924
Print/Reprint Date: 01/21/2025

Jonathan B. Perlin, MD, PhD, MSHA, MACP, FACMI
President and Chief Executive Officer

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.

This reproduction of the original accreditation certificate has been issued for use in regulatory/payer agency verification of accreditation by The Joint Commission.

American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc.

hereby accredits that

Graymont Medical
1622 W Carroll Ave, Chicago, IL

having successfully met the facility accreditation requirements of this Board, which establishes and advocates for the highest patient care standards in the provision of orthotic, prosthetic and pedorthic services, is hereby declared to be a facility accredited in

Orthotics & Durable Medical Equipment

Accreditation Period
September 23, 2023 – October 31, 2026

Richard A. Babcock, CO
President

0112

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Graymont Equipment Distribution, LLC MDEG License # (if applicable) _____

Physical Address 2214 W Hubbard St

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 312-291-9305 Website www.graymontmedical.com

Licensing Company Email Compliance@graymontmedical.com

Section 2: Personal Information

First Kara Middle Ashley Last Albert

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

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

Mailing Address [redacted]

City [redacted] State IL Zip [redacted]

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Westminster College		09/2000 - 05/2004	
Address: 501 Westminster Ave	City: Fulton	State: MO	Zip: 65251
Diploma/Degree obtained, if any: Bachelor of Arts, Psychology			

School Name		From - To (MM/YY – MM/YY)	
Fulton High School		09/1996 - 05/2000	
Address: #1 Hornet Drive	City: Fulton	State: MO	Zip: 65251
Diploma/Degree obtained, if any: High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/2021 - Present	[redacted]	Chicago	IL	[redacted]
6/2019 - 6/2021		Chicago	IL	
1/2017 - 6/2019		Chicago	IL	
8/2011 - 1/2017		Chicago	IL	

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

Business Name		From - To (MM/YY – MM/YY)	
Graymont Equipment Distribution, LLC		05/22 - PRESENT	
Business Address	**City**	**State**	**Zip**
2214 W Carroll Ave	Chicago	IL	60612
Phone	**Title**	**Number of Employed Hours**	
312-291-9305	Chief Operating & People Officer	5,000+	
Description of Duties			
Manage and oversees the operations and human capital for all employees nationwide. Develops and leads organizational initiatives including performance management, hiring, development, training, compliance, contracting etc.			

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

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

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

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

Continue on next page if additional space is needed.

NA

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

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

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

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

Provide explanation below:

NA

_____ _____

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

I, Kara Albert, **certify that as the MDEG Administrator for**

Graymont Equipment Distribution, LLC,

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

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

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

Kara Albert

Print Name (First, Last)

Kara Albert

Original Signature (electronic, copies or stamps not accepted)

2/10/2025

Date

Board Use Only	Date Received: 2/24/25

20%

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Graymont Equipment Distrbution, LLC

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

Physical Address 2214 W Hubbard St

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 312-291-9305 Website www.graymontmedical.com

Licensing Company Email Compliance@graymontmedical.com

Section 2: Personal Information

First Nick Middle THOMAS Last Wright

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

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

Mailing Address [redacted]

City [redacted] State IL Zip [redacted]

Telephone [redacted] Email [redacted]

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

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

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

98 - 02

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

School Name		From - To (MM/YY – MM/YY)	
MICHIGAN STATE UNIVERSITY		08/98 - 05/02	
Address	**City**	**State**	**Zip**
426 AUDITORIUM RD	EAST LANSING	MI	58824
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE - BUSINESS/ACCOUNTING			

School Name		From - To (MM/YY – MM/YY)	
PLYMOUTH-CANTON HIGH SCHOOL		08/94 - 06/98	
Address	**City**	**State**	**Zip**
8400 N BECK RD	CANTON	MI	48187
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/13 - PRESENT	[redacted]	CHICAGO	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
GRAMMONT EQUIPMENT DISTRIBUTION, LLC			03/12 - PRESENT	
Business Address	**City**	**State**	**Zip**	
2214 W HUBBARD ST	CHICAGO	IL	60612	
Phone	**Title**			
312-291-9305	MEMBER/OWNER			
Description of Duties				
MEMBER, OVERSEES STRATEGIC DIRECTION				

Business Name			From - To (MM/YY – MM/YY)	
THE LACTATION NETWORK, LLC			09/17 - PRESENT	
Business Address	**City**	**State**	**Zip**	
1621 W CARROLL AVE	CHICAGO	IL	60612	
Phone	**Title**			
888-510-0059	MEMBER/OWNER			
Description of Duties				
CO-FOUNDER, OVERSEES STRATEGIC DIRECTION				

Business Name			From - To (MM/YY – MM/YY)	
ASHLAND HEALTH LLC			01/14 - PRESENT	
Business Address	**City**	**State**	**Zip**	
1621 W CARROLL AVE	CHICAGO	IL	60612	
Phone	**Title**			
888-510-0059	MEMBER/OWNER			
Description of Duties				
CO-FOUNDER, OVERSEES STRATEGIC DIRECTION				

Business Name			From - To (MM/YY – MM/YY)	
GRAMMONT PROFESSIONAL PRODUCTS IP, LLC			06/18 - PRESENT	
Business Address	**City**	**State**	**Zip**	
2216 W HUBBARD ST	CHICAGO	IL	60612	
Phone	**Title**			
312-291-9305	MEMBER/OWNER			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
MIDWAY MEDICAL, LLC			05/15 - PRESENT	
Business Address	**City**	**State**	**Zip**	
3004 GILL ST	BLOOMINGTON	IL	61704	
Phone	**Title**			
844-436-9290	MEMBER/OWNER			
Description of Duties				

Continue on next page if additional space is needed.

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

NA

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

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

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

Provide explanation below:

_____ _____

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

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

NICK WRIGHT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2025

Date

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

State of ILLINOIS, ss. County of COOK

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

Original Signature

2/11/2025

Date

Subscribed and Sworn to before me this 11TH day of 2025.

Notary Public Signature

OFFICIAL SEAL
ALLISON SORENSON
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires Feb 8, 2028

(Seal)

35%.

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Graymont Equipment Distribution, LLC

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

Physical Address: 2214 W Hubbard St

City: Chicago State: IL Zip: 60612

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 312-291-9305 Website: www.graymontmedical.com

Licensing Company Email: compliance@graymontmedical.com

Section 2: Personal Information

First: Bryce Middle: Alan Last: Beasley

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

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

Mailing Address: [redacted]

City: [redacted] State: IL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
The University of Kansas		08/04 - 05/08	
Address	**City**	**State**	**Zip**
1450 Jayhawk Blvd	Lawrence	KS	66045
Diploma/Degree obtained, if any			
Bachelor of Science in Journalism: Marketing, Sales & Advertising			

School Name		From - To (MM/YY – MM/YY)	
Blue Valley North High School		08/00 - 06/04	
Address	**City**	**State**	**Zip**
12200 Lamar Ave	Overland Park	KS	66209
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - PRESEN	[redacted]	Western Springs	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	
12/15 05/19		CHICAGO	IL	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Graymont Medical			07/12 - CURRENT
Business Address	**City**	**State**	**Zip**
2214 W Hubbard St	Chicago	IL	60612
Phone	**Title**		
312-291-9305	Chief Executive Officer		
Description of Duties			
Sales Representative, Director of Sales, Chief Revenue Officer, and Chief Executive Officer.			

Business Name			From - To (MM/YY – MM/YY)
Smith + Nephew			07/12 - CURRENT
Business Address	**City**	**State**	**Zip**
150 Minuteman Road	Andover	MA	01810
Phone	**Title**		
978-749-1000	Distributor Executive		
Description of Duties			
Medical Device Sales Rep/ Field Sales Trainer, Director of Sales and Distributor Executive.			

Business Name			From - To (MM/YY – MM/YY)
GRAYMONT PROFESSIONAL PRODUCTS IP, LLC			05/23-CURRENT
Business Address	**City**	**State**	**Zip**
2216 W HUBBARD ST	CHICAGO	IL	60612
Phone	**Title**		
312-291-9305	MEMBER/OWNER		
Description of Duties			
OVERSEES/PROVIDES STRATEGIC DIRECTION TO THE ORGANIZATION.			

Business Name			From - To (MM/YY – MM/YY)
MIDWAY MEDICAL			05/23 – CURRENT
Business Address	**City**	**State**	**Zip**
3004 GILL ST.	BLOOMINGTON	IL	61704
Phone	**Title**		
844-436-9290	MEMBER/OWNER		
Description of Duties			
OVERSEES/PROVIDES STRATEGIC DIRECTION TO THE ORGANIZATION.			

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

Continue on next page if additional space is needed.

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

NA

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

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

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

BRYCE BEASLEY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/25

Date

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

State of ILLINOIS, ss. County of COOK

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

Original Signature

2/11/25

Date

Subscribed and Sworn to before me this 11TH day of FEBRUARY

Notary Public Signature

OFFICIAL SEAL
ALLISON SORENSON
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires Feb 8, 2028

(Seal)

45%.

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Graymont Equipment Distribution, LLC

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

Physical Address 2214 W Hubbard St

City Chicago State IL Zip 60612

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 312-291-9305 Website www.graymontmedical.com

Licensing Company Email compliance@graymontmedical.com

Section 2: Personal Information

First Nathan Middle Charles Last Gray

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

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

Mailing Address [redacted]

City [redacted] State IL Zip [redacted]

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Michigan State University		9/98 – 6/2002	
Address	**City**	**State**	**Zip**
426 Auditorium Road	East Lansing	MI	48824
Diploma/Degree obtained, if any			
NA			

School Name		From - To (MM/YY – MM/YY)	
Plymouth Salem HIGH SCHOOL		09/93 – 6/97	
Address	**City**	**State**	**Zip**
46181 JOY RD	CANTON	MI	48187
Diploma/Degree obtained, if any			
HIGH SCHOOL DEGREE			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/16-PRESENT	[redacted]	Western Springs	IL	[redacted]
04/10-03/16	[redacted]	Western Springs	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Graymont Equipment Distribution, LLC			03/12- PRESENT	
Business Address	**City**	**State**	**Zip**	
2214 W Hubbard St	Chicago	IL	60612	
Phone	**Title**			
312-291-9305	Member/ Owner			
Description of Duties				
Co-Founder/ responsible for overseeing and providing strategic direction to the organization.				

Business Name			From - To (MM/YY – MM/YY)	
The Lactation Network, LLC			09/17 - PRESENT	
Business Address	**City**	**State**	**Zip**	
1621 W Carroll Ave	Chicago	IL	60612	
Phone	**Title**			
888-510-0059	Member/ Owner			
Description of Duties				
Co-Founder/ responsible for overseeing and providing strategic direction to the organization.				

Business Name			From - To (MM/YY – MM/YY)	
Graymont Professional Products IP, LLC			06/18- PRESENT	
Business Address	**City**	**State**	**Zip**	
2216 W Hubbard St	Chicago	IL	60612	
Phone	**Title**			
312-291-9305	Member/ Owner			
Description of Duties				
Co-Founder/ responsible for overseeing and providing strategic direction to the organization.				

Business Name			From - To (MM/YY – MM/YY)	
Ashland Health LLC			01/14- PRESENT	
Business Address	**City**	**State**	**Zip**	
1621 W Carroll Ave	Chicago	IL	60612	
Phone	**Title**			
888-510-0059	Member/ Owner			
Description of Duties				
Co-Founder/ responsible for overseeing and providing strategic direction to the organization.				

Business Name			From - To (MM/YY – MM/YY)	
Smith + Nephew			05/02- 12/22	
Business Address	**City**	**State**	**Zip**	
150 Minuteman Road	Andover	MA	01810	
Phone	**Title**			
978-749-1000	Independent Distributor			
Description of Duties				
Transitioned from Sales Representative to Independent Distributor of Greater Chicagoland Territory				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Midway Medical, LLC			05/15-PRESENT
Business Address	**City**	**State**	**Zip**
3004 Gill Street	Bloomington	IL	61704
Phone	**Title**		
844-436-9290	Member/ Owner		
Description of Duties			
Co-Founder/ responsible for overseeing and providing strategic direction to the organization			

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

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

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

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

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

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

NA

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

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

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

Provide explanation below:

NA

_____ _____

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

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

Nathan Gray

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/18/2025

Date

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

State of ILLINOIS, ss. County of COOK

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

Original Signature

2/18/2025

Date

Subscribed and Sworn to before me this 18TH day of FEBRUARY 2025

Notary Public Signature

OFFICIAL SEAL
ALLISON SORENSON
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires Feb 8, 2028

(Seal)

4D

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: Cardinal Health 414, LLC

Physical Address: 850 Corduroy Rd., Suite 100

City: Lewis Center State: Ohio Zip: 43035

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

City: Dublin State: Ohio Zip: 43017

Telephone: 740-204-2640 Website: www.CardinalHealth.com

Name of Designated Representative (DR): Norman Lott

Licensing Company Email: Norman.Lott@CardinalHealth.com DR Email: Norman.Lott@CardinalHealth.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: radiopharmaceuticals	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

This summary is provided in response to our affirmative answer to the disciplinary history question on our application. Please note that, based on the broadness of the application question; we are disclosing all discipline that has occurred at other Cardinal Health Nuclear Pharmacy sites within the past 5 years. None of the below citations involved the Cardinal Health facility located in Lewis Center, OH, the site to which this application pertains. The safety of the nation's pharmaceutical supply chain is among our highest priorities. We take this responsibility very seriously and work diligently to comply with all applicable laws and regulations governing pharmacy. If you have any questions specific to these matters, please contact Dawn Harmon at (614) 757-7570.

2024-Virginia Board of Pharmacy

Actions Taken: Consent Order

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Charlottesville, VA

Violation that Occurred-During an October 4, 2023, inspection conducted by the Virginia Board of Pharmacy ("Board"), the Board noted that the pharmacy removed a 360-degree motion sensor in the anteroom and replaced the same with up a 180-degree motion sensor, without submitting a remodel application to obtain Board approval. In addition, the Board noted certain walls contained areas with cracks that were not sealed, while some wall repairs were not painted so they were not smooth and impervious.

Final Disposition: Agreed to Consent Order, paid fine, submitted remodel application, and fixed walls according to Board requirements.

Effective Date: 02/09/2024

Fines: $2,250.00

2020-Michigan Department of Licensing and Regulatory Affairs

Actions Taken: Consent Order

Location Involved: Cardinal Health 414, LLC, radiopharmacy in Southfield, MI

Final Disposition: This settlement concerns a divergence of opinion concerning the application of a recently enacted statute to the operation of nuclear pharmacy. While a nuclear pharmacy prepares sterile radiopharmaceuticals, it does not do so by the statutory definition of compounding and therefore not subject to the external certification required by the statutory language for pharmacies that compound. The consent order represents an agreement to disagree on the application of the statute to nuclear pharmacy, but to agree to the external certification of the pharmacy.

Effective date: 06/10/2020

Fine: $500

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
06/06/2019	06/10/2020	MI	Southfield	Oakland

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
53-18-154238	Michigan Dept of Licensing and Regulatory Affairs

Reason/Charge
External certification not obtained as required by the board of pharmacy

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Cardinal Health 414, LLC- nuclear pharmacy-Southfield, MI	Consent Order

Name of Business/Industry/Entity
Cardinal Health 414, LLC- nuclear pharmacy located in Southfield, Michigan

Provide explanation below:

This settlement concerns a divergence of opinion concerning the application of a recently enacted statute to the operation of nuclear pharmacy. While a nuclear pharmacy prepares sterile radiopharmaceuticals, it does not do so by the statutory definition of compounding and therefore not subject to the external certification required by the statutory language for pharmacies that compound. The consent order represents an agreement to disagree on the application of the statute to nuclear pharmacy, but to agree to the external certification of the pharmacy. Fine was paid in the amount of $500.00

Original Signature (electronic, copies or stamps not accepted)

1-30-2025
Date

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

CARDINAL HEALTH 414, LLC
License No. 53-01-007670,

File No. 53-18-154238

Respondent.

CONSENT ORDER AND STIPULATION

CONSENT ORDER

On June 6, 2019, the Department of Licensing and Regulatory Affairs executed an Administrative Complaint charging Respondent with violating the Public Health Code, MCL 333.1101 *et seq*.

The parties have stipulated that the Disciplinary Subcommittee of the Michigan Board of Pharmacy may enter this Consent Order. The Disciplinary Subcommittee of the Michigan Board of Pharmacy has reviewed this Consent Order and Stipulation and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violations of MCL 333.17748a(2), MCL 333.17768(1), and Mich. Admin. Code, R 338.490(1).

Accordingly, IT IS ORDERED that for the cited violations of the Public Health Code, Respondent is placed on PROBATION for a minimum of one day and not to exceed six months, commencing on the effective date of this Order. The terms of probation shall be as follows:

1. NATIONAL ACCREDITATION: Respondent Pharmacy will be accredited by a national accrediting organization, as specified in MCL 333.17748(a)(2).

2. COSTS: Respondent shall be solely responsible for payment of all costs incurred in complying with the terms of this Order.

Respondent shall be automatically discharged from probation upon receipt by the Department of satisfactory evidence of the successful completion of the probationary terms as set forth above, PROVIDED compliance occurs within six (6) months, Respondent has paid the fine set forth below, has complied with the terms of this Order and has not violated the Public Health Code.

Respondent shall comply with all applicable provisions of the Public Health Code and rules promulgated thereunder.

If Respondent has not obtained accreditation within the six month probationary period, Respondent's license shall be suspended until accreditation is obtained. Reinstatement from this suspension shall be automatic unless the suspension lasts for more than six (6) months. If the suspension lasts for longer than six (6) months, Respondent may apply for reinstatement pursuant to MCL 333.16245 and 16247 and

Mich Admin Code, R 792.10711. Under these provisions, Respondent must demonstrate the following by clear and convincing evidence: (1) good moral character; (2) the ability to practice the profession with reasonable skill and safety; (3) satisfaction of the guidelines on reinstatement adopted by the Department; and (4) that it is in the public interest for the license to be reinstated.

Respondent shall direct any communications to the Department that are required by the terms of this order to: **BPL-Monitoring@michigan.gov** or by mail to **Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30670, Lansing, MI 48909.**

If Respondent violates any provision of this Order, the DSC may take disciplinary action pursuant to Mich Admin Code, R 338.1632 and MCL 333.16221(h).

Respondent is FINED five-hundred dollars ($500.00), to be paid to the State of Michigan within 90 days of the effective date of this Order. Respondent shall direct payment to the Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909. The fine shall be paid by check or money order, made payable to the State of Michigan, and shall clearly display **File Number 53-18-154238.**

This Order shall be effective 30 days from the date signed by the Board, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____ for
Chairperson, Disciplinary Subcommittee

Dated: June 10, 2020

STIPULATION

1. Respondent does not contest the allegations of fact and law in the Complaint. Respondent understands that, by pleading no contest, Respondent does not admit the truth of the allegations but agrees the Disciplinary Subcommittee of the Michigan Board of Pharmacy may treat the allegations as true for the resolution of the complaint and may enter an order treating the allegations as true. Therefore, the Disciplinary Subcommittee of the Michigan Board of Pharmacy finds that the facts alleged in the Complaint are true and constitute violations of MCL 333.17748a(2), MCL 333.17768(1), and Mich. Admin. Code, R 338.490(1).

2. Respondent understands and intends that by signing this Stipulation, Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq*, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq*; and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law.

4. James Stevenson, R.Ph., served as conferee and supports this resolution. Mr. Stevenson and the Department took the following factors into consideration in the formulation of this Order are:

a. During a compliance conference between the parties, Respondent's PIC stated that they were in the process of obtaining accreditation and submitted evidence of such.

b. Respondent's PIC provided evidence of policy changes to correct the deficiencies identified in the inspection.

c. Respondent's PIC maintained the position that they were reconstituting drugs and not engaged in sterile compounding. Additionally, the PIC stated that the variances in expiration times did not constitute sterile compounding.

d. During the Compliance Conference, Respondent's PIC detailed efforts he has made to maintain a safe environment for reconstituting drugs and that the processes that they are following have been tested verified by other sources.

5. A Department representative may discuss this matter with the DSC and recommend acceptance of the resolution set forth in this Order.

6. This proposal is conditioned upon acceptance by the DSC. Respondent and the Department expressly reserve the right to further proceedings without prejudice should the Order be rejected.

AGREED TO BY:

Forrest Pasanski, Director
Enforcement Division
Bureau of Professional Licensing

Dated: 3-30-2020

AGREED TO BY:

Cardinal Health 414, LLC
Respondent

By: Paul Gotti

Its: VP Operations

Dated: March 9, 2020

ses

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/04/2023	02/09/2024	VA	Charlottesville	Charlottesville City

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
232930	Commonwealth of Virginia Dept of Health Professions

Reason/Charge
pharmacy remodeled without submitting application/walls with cracks that were not sealed

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Cardinal Health 414, LLC- nuclear pharmacy-Charlottesville, VA	Consent Order

Name of Business/Industry/Entity
Cardinal Health 414, LLC- nuclear pharmacy located in Charlottesville, VA

Provide explanation below:

During an October 4, 2023, inspection conducted by the Virginia Board of Pharmacy (" Board "), the Board noted that the pharmacy removed a 360-degree motion sensor in the anteroom and replaced the same with up a 180-degree motion sensor, without submitting a remodel application to obtain Board approval. In addition, the Board noted certain walls contained areas with cracks that were not sealed, while some wall repairs were not painted so they were not smooth and impervious. Agreed to Consent Order, paid fine $ 2,250.00, submitted remodel application, and fixed walls according to Board requirements.

Original Signature (electronic, copies or stamps not accepted)

1-30-2025
Date

0201003691

COMMONWEALTH of VIRGINIA

Arne W. Owens
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
PHONE (804) 367- 4400

Board of Pharmacy
804/367-4456
804-799-7906 (fax)

February 12, 2024

Cardinal Health 414, LLC
Jeffrey Scott Mitchell, Pharmacist-in-Charge
Mailed to the legal address of record
with the Board of Pharmacy

RE: Case #232930

Dear Jeffrey Scott Mitchell:

Enclosed please find a certified true copy of the Inspection Deficiency Notice and Consent Order that was entered by the Board on February 9, 2024. Further, this confirms receipt of the monetary penalty and the documentation indicating the corrective action taken. As all requirements have been satisfied, the case is now closed.

Sincerely,

Rose E. DeMatteo
Compliance Case Manager

Enclosure

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov
October 4, 2023

DHP – MAILROOM
NOV 0 2 2023

Received
VA Board of Pharmacy
NOV 06 2023

Cardinal Health 414, LLC
Permit Number: 0201003691

Notice

After an inspection conducted on October 4, 2023, at Cardinal Health 414, LLC, the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. ($250) Deficiency 7: Remodel of pharmacy without submitting application or Board approval; 18 VAC 110-20-140
2. ($2,000) Deficiency 32: Have clean room, but not all physical standards in compliance, e.g., wall, ceiling; § 54.1-3410.2

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of $2,250.00 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder

may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

Consent Order

The Virginia Board of Pharmacy ("Board") and Cardinal Health 414, LLC. ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on October 4, 2023.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of $2,250.00 to the Board within 30 days of the date of the Notice.

2. Pharmacy shall submit documentation of immediate action taken to correct all violations.

3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

Signature of PIC or Owner — Date: 27 Oct 2023

Printed Name of Person Signing: Jeffrey S. Mitchell — Position/Title: RPh, PIC

FOR THE BOARD:

Caroline D. Juran, Executive Director — Entered: 21912024

CERTIFIED TRUE COPY
BOARD OF PHARMACY

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov

CONFIDENTIAL

Complete and return with the
Inspection Deficiency Notice and Consent Order

Pharmacy Name: Cardinal Health 414, LLC

Permit Number: 0201003691

FEIN: 31-0958666 85-0229124

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico Virginia 23233

Actions to be Taken When Provided an Inspection Deficiency Notice and Consent Order Resulting from a Routine Inspection

1. Do not record information on or make changes to the Inspection Deficiency Notice and Consent Order. This is a formal document issued on behalf of the Board.
2. The following actions may be taken.
    a. If the owner or PIC agrees with the deficiencies:
        i. The owner or PIC must sign and date the document, print name, and record position/title; and,
        ii. Within 30 days, submit the following as **one mailing:**
            1. **all** pages of the **ORIGINAL** signed Inspection Deficiency Notice and Consent Order;
            2. check or money order made payable to the "Treasurer of Virginia"; and,
            3. written documentation that the deficiencies have been corrected.
    b. If the owner or PIC does not agree with the deficiencies:
        i. Within 14 days, submit documentation contesting the inspector's findings; OR,
        ii. Request, in writing, an informal conference to further discuss the matter before a committee of the Board.
3. Failure to respond to the Inspection Deficiency Notice and Consent Order within 30 days will automatically result in the scheduling of an informal conference. The owner or PIC may be subject to disciplinary sanctions by the Board in addition to those listed in the Inspection Deficiency Notice and Consent Order.
4. Complete the CONFIDENTIAL document by providing the pharmacy's Federal Employee Identification Number (FEIN). Submit this document with your Inspection Deficiency Notice and Consent Order.
5. Contact Ellen Shinaberry at (804) 367-4456 should you have any questions regarding the Inspection Deficiency Notice and Consent Order. Please do not contact the inspector.

REORDER FOR U.S. PATENT NO. [illegible]

CardinalHealth

Cardinal Health, Expense
PO Box 3813
Dublin,OH 43016-3813
800.903.6343 - Option 4

10880886
DATE: 10/31/2023
VENDOR NO: 5000036608

VIRGINIA, TREASURER OF
9960 MAYLAND DR STE 300
23233 HENRICO-HENRICO

DATE	DESCRIPTION	GROSS AMOUNT	CASH DISCOUNT	NET AMOUNT
10/04/2023	INV# 0201003691N1023 NConsentOrder7222	2,250.00	0.00	2,250.00
		2,250.00	0.00	2,250.00

THIS CHECK IS VOID WITHOUT A RED & BLUE BORDER AND BACKGROUND PLUS A KNIGHT & FINGERPRINT WATERMARK ON THE BACK - HOLD AT ANGLE TO VIEW

10880886

CardinalHealth

Cardinal Health, Expense
PO Box 3813
Dublin, OH 43016-3813
800.903.6343 - Option 4

64-975
612

Date 10/31/2023

VIRGINIA, TREASURER OF
9960 MAYLAND DR STE 300
HENRICO VA 23233

PAY TO THE ORDER OF

TWO THOUSAND TWO HUNDRED FIFTY Dollars

$ *********2,250.00

Scott B Z

Wells Fargo Bank, N.A

Memo

AUTHORIZED SIGNATURE

⑈10880886⑈ [redacted] [redacted]

ORIGIN ID:CMHA (614) 757-7570
DAWN HARMON
CARDINAL HEALTH
7000 CARDINAL PLACE
DUBLIN, OH 43017
UNITED STATES US

SHIP DATE: 01NOV23
ACTWGT: 1.00 LB
CAD: 104744132/INET4535

BILL SENDER

TO **BOARD OF PHARMACY**
COMMONWEALTH OF VIRGINIA
9960 MAYLAND DRIVE, SUITE 300

HENRICO VA 23233
(804) 367-4456
INV:
PO:
REF:
DEPT:

583J4/C5BD/9AE3

FedEx Express

JZ340Z2310159luv

THU - 02 NOV 10:30A
PRIORITY OVERNIGHT

TRK# 0201 7739 3472 2262

XS LFIA

23233
VA-US RIC

After printing this label:
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1. Fold the printed page along the horizontal line
2. Place label in shipping pouch and affix it to your shipment.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

Virginia Department of
Health Professions
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov
www.dhp.virginia.gov/pharmacy

APPLICATION FOR A PHARMACY PERMIT

Check Appropriate Box(es):

☐ New[3, 4]	$500.00	☐ Change of Pharmacist-In-Charge[2, 4]	$65.00
☐ Change of Ownership[2]	$65.00	☐ Change of Location[3]	$300.00
☐ Change of Pharmacy Name[2]	No Fee	☒ Remodeling of Prescription Dept.[3]	$300.00
☐ Reinstatement[1, possibly 3]	Call Board		

[1] If reinstatement, due to: ☐ Lapse of Permit or ☐ Suspension or Revocation of a Permit

Application fees are not refundable. Applications are valid for one year from the date of receipt. The required fees must accompany the application. Make check payable to "Treasurer of Virginia". Send ORIGINAL application to the Board for processing.

Name of Pharmacy Cardinal Health 414, LLC			Area Code and Telephone Number 434-984-1225
Street Address 713-B Harris Street			Area Code and Fax Number 434-984-1228
City Charlottesville		State Virginia	Zip Code 22903
If a current pharmacy permit is held, indicate the permit number **0201**-003691	Telephone Number (currently working number) 434-984-1225	Federal Employment Identification Number (FEIN) 85-0229124	
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming) Jeffrey Mitchell		License Number of the PIC **0202**-207660	
Signature of PIC – if change of PIC, incoming signature Jeffrey D. Mitchell		[2] Effective Date of Change (if change of PIC, date assuming role as PIC) N/A	
By affixing my signature I acknowledge that I have read and understood Guidance Document 110-27 and associated information regarding the inspection process.		Expected Hours of Operation:	

[4] Has the pharmacist obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another U.S. jurisdiction? If yes, please provide the information below (attach separate sheet if needed): Yes ☒ No ☐

Pharmacy name	Pharmacy address	Date range of practice
Pharmacy Name:	Pharmacy Address:	Date range of practice:

E-mail address for Pharmacist-In-Charge jeff.mitchell@cardinalhealth.com	[3] Expected Opening, Moving, or Completion Date already open	[3] Requested Inspection Date occurred on 10/04/2023

[3] **A 14-day notice is required for scheduling an inspection. Drugs may not be stocked prior to inspection and approval.** An inspector will call prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

OWNERSHIP TYPE—check one:	Corporation ☐	Partnership ☐	Individual ☐	Other ☒ LLC
Name of ownership entity if different from name of application:				
Street Address: 7000 Cardinal Place, Q&R Dept NPS			Phone No. 614-757-7570	
City: Dublin		State: Ohio	Zip Code: 43017	
State(s) of incorporation: Delaware				

List all other trade or business names used by this facility

Name: Cardinal Health **Name:** _____

Name: _____ **Name:** _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED ☒

Name: _____ Title: _____

Residence Address: _____

Name: _____ Title: _____

Residence Address: _____

LIST OF PHARMACISTS PRACTICING AT THIS PHARMACY OTHER THAN PIC OR LIST IS ATTACHED ☐

Name: Craig Hansen License No. **0202-** 208253

Name: Syed Haq License No. **0202-** 212977

Please answer the following questions:

1. Does the pharmacy engage in the compounding of **HIGH RISK STERILE** drug products?	Yes ☐ No ☒
2. Does the pharmacy engage in the compounding of **MEDIUM RISK STERILE** drug products?	Yes ☐ No ☒
3. Does the pharmacy engage in the compounding of **LOW RISK STERILE** drug products?	Yes ☒ No ☐
4. Does the pharmacy engage in the compounding of **NON-STERILE** drug products?	Yes ☒ No ☐
5. Does the pharmacy share or intend to share the same physical space with an outsourcing facility? If yes, all compounding must be performed in compliance with cGMPs and the facility must also obtain a permit as an outsourcing facility.	Yes ☐ No ☒

FOR OFFICE USE ONLY:

Date processed:	Check No:	Receipt No:	Application No:	
Permit Number: 0201-	Date sent to Enforcement:	Date sent to PMP:	Reviewed by:	Date Issued:

ORIGIN ID:CMHA (614) 757-7570
DAWN HARMON
CARDINAL HEALTH
7000 CARDINAL PLACE

DUBLIN, OH 43017
UNITED STATES US

SHIP DATE: 01NOV23
ACTWGT: 1.00 LB
CAD: 104744132/INET4535

BILL SENDER

TO **BOARD OF PHARMACY**
COMMONWEALTH OF VIRGINIA
9960 MAYLAND DRIVE, SUITE 300

HENRICO VA 23233
(804) 367-4456 REF:
INV:
PO: DEPT:

583J4/C5BD/9AE3

FedEx Express

E

J23A0231015/1ov

THU - 02 NOV 10:30A
PRIORITY OVERNIGHT

TRK# 0201 7739 3472 2262

XS LFIA

23233
VA-US RIC

After printing this label:
CONSIGNEE COPY - PLEASE PLACE IN FRONT OF POUCH
1. Fold the printed page along the horizontal line.
2. Place label in shipping pouch and affix it to your shipment.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

RECORDER 800 U.S. PATENT NO 5536290 5575908 5641186 5765325 5846384 [illegible]

CardinalHealth

Cardinal Health, Expense
PO Box 3813
Dublin,OH 43016-3813
800.903.6343 - Option 4

10880885
DATE: 10/31/2023
VENDOR NO: 5000036608

VIRGINIA, TREASURER OF
9960 MAYLAND DR STE 300
23233 HENRICO-HENRICO

DATE	DESCRIPTION	GROSS AMOUNT	CASH DISCOUNT	NET AMOUNT
10/27/2023	INV# 0201003691REM23 NRemodelapp	300.00	0.00	300.00
		300.00	0.00	300.00

THIS CHECK IS VOID WITHOUT A RED & BLUE BORDER AND BACKGROUND PLUS A KNIGHT & FINGERPRINT WATERMARK ON THE BACK - HOLD AT ANGLE TO VIEW

10880885

64-975
612

CardinalHealth

Cardinal Health, Expense
PO Box 3813
Dublin, OH 43016-3813
800.903.6343 - Option 4

Date 10/31/2023

VIRGINIA, TREASURER OF
9960 MAYLAND DR STE 300
HENRICO VA 23233

PAY TO THE ORDER OF

THREE HUNDRED Dollars

$ **********300.00

Scott B Z

Wells Fargo Bank, N.A

Memo

AUTHORIZED SIGNATURE

⑈10880885⑈ [redacted] [redacted]

FedEx.

November 03, 2023

Dear Customer,

The following is the proof-of-delivery for tracking number: 773934722262

Delivery Information:

Status:	Delivered	**Delivered To:**	Mailroom
Signed for by:	S.MCKINNEY	**Delivery Location:**	9960 MAYLAND DR 300
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		HENRICO, VA, 23233
		Delivery date:	Nov 2, 2023 10:28

Shipping Information:

Tracking number:	773934722262	**Ship Date:**	Nov 1, 2023
		Weight:	0.5 LB/0.23 KG

Recipient:
Board of Pharmacy, Commonwealth of Virginia
9960 Mayland Drive, Suite 300
HENRICO, VA, US, 23233

Shipper:
Dawn Harmon, Cardinal Health
7000 Cardinal Place
Dublin, OH, US, 43017

Thank you for choosing FedEx

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Jubilant RadioPharma Kirkland, Montreal, Quebec, H9H 4J4, Canada
Address: 16751 TransCanada Highway City: State: Zip:

Name: Curium
Address: 111 West Port Plaza, Suite 800 City: Saint Louis State: MO Zip: 63146

Name: GE HealthCare
Address: 251 Locke Drive City: Marlborough State: MA Zip: 01752

Name: Sun RadioPharma
Address: 29 Dunham Road City: Billercia State: MA Zip: 01821

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Cardinal Health, Inc
Corporation Name: Cardinal Health, Inc
Mailing Address: 7000 Cardinal Place
City: Dublin State: Ohio Zip: 43017
Telephone: 614-757-7570 Email: Dawn.Harmon@CardinalHealth.com
Contact Person Name: Dawn Harmon

Date of SEC Registration: 06/30/2007 | SEC Registration Number: 2007043108722 | Stock Exchange Symbol: CAH

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NOT APPLICABLE
Parent Company (if any): NOT APPLICABLE
Corporation/Organization Name: NOT APPLICABLE
Mailing Address: NOT APPLICABLE
City: NOT APPLICABLE State: N/A Zip: N/A
Telephone: NOT APPLICABLE Email: NOT APPLICABLE
Contact Person Name: NOT APPLICABLE

Section 6: Partnership

Partnership Name: NOT APPLICABLE
Mailing Address: NOT APPLICABLE
City: NOT APPLICABLE State: N/A Zip: N/A
Telephone: NOT APPLICABLE Email: NOT APPLICABLE
Contact Person Name: NOT APPLICABLE

Section 7: Sole Owner

Owner's Name: NOT APPLICABLE
Business Name: NOT APPLICABLE
Business Address: NOT APPLICABLE
City: NOT APPLICABLE State: N/A Zip: N/A
Telephone: NOT APPLICABLE Email: NOT APPLICABLE

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cardinal Health 414, LLC

Facility Name

Norman Lott

Print Name of Authorized Person Submitting Application

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

01-29-2025

Date

Board Use Only	Date Received: 2/12/25	Amount: $1000.00

CardinalHealth

850 Corduroy Rd
Suite 100
Lewis Center, Ohio 43035

Officer Name	title
Paul Michael Friedenberg	VP Operations
Paul Gotti	Vice President-Operations
Michael Francis Pintek	President
David William Pellicciarini	VP Pharmacy Safety,Practice and Technical Operations NPHS

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Shareholders: Cardinal Health, Inc.

Name	Equities	%	Valuation
Vanguard Fiduciary Trust Co.	30,792,977	12.72 %	3 642 M $
BlackRock Advisors LLC	23,693,180	9.790 %	2 802 M $
STATE STREET CORPORATION	14,177,641	5.858 %	1 677 M $
Geode Capital Management LLC	5,749,859	2.376 %	680 M $
BlackRock Life Ltd.	5,263,810	2.175 %	623 M $

» List of CARDINAL HEALTH, INC. shareholders

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CARDINAL HEALTH 414, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Charuni Patibanda-Sanchez, Secretary of State

2073291 8300

Authentication: 202949748

SR# 20250568167

Date: 02-17-25

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

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

Cardinal Health 414, LLC

Cardinal Health 414, LLC

850 Corduroy Rd., Suite 100

Lewis Center, OH 43035

License Number: 0130000367

Wholesaler - Category 2

Expiration Date: June 30, 2025

CLASS: Wholesaler - Category 2
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
NORMAN LOTT	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Have a licensing question? Contact your licensing board or check their website. Help desk representatives are not trained to answer licensing questions.

Technical Support - Help desk representatives are available to answer login or registration questions by calling (855) 405-5514 weekdays from 8:00 am to 5:00 pm EST.

Callers may experience extended wait times due to the high number of calls. If you're unable to wait for a representative, you can leave a call back number.
If you're experiencing technical issues with the eLicense website, make sure you are using Google Chrome or Mozilla Firefox as your browser on a desktop or laptop device.

License Look Up

PRINTER FRIENDLY VERSION

Cardinal Health 414, LLC

The search results for the license holder are listed to the right.

Current Date & Time
1/28/2025 9:15 AM

Status
Active

Sub-Status

Sub-Category
FS – Full Service

Board
Board of Pharmacy

License Type
Wholesaler - Category 2

License Number

0130000367

License Issue Date

07/15/2021

License Effective Date

07/01/2023

License Expiration Date

06/30/2025

Street Address

850 Corduroy Rd., Suite 100

Zipcode

43035

City

Lewis Center

State

OH

Country

United States

Board Action

No

Current date & time: **1/28/2025 9:15 AM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

SUPPORT (OH_SUPPORTPAGE)

REGISTRATION GUIDE (/SERVLET/SERVLET.FILEDOWNLOAD?FILE=015T0000000UG2L)

CONTACT (OH_CONTACTUS)

PRIVACY NOTICE (OH_PRIVACYNOTICE)

WWW.OHIO.GOV (HTTP://WWW.OHIO.GOV)

GENERAL TERMS (OH_GENERALTERMS)

Employee list
Norman Lott
Jason Hinton
Benjamin Fischer
Sinit Streets
Jeff Mould
Brett Powell
Brian Briones
Mike Weiss
Andy Owens

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 1-11373

Cardinal Health, Inc.

(Exact name of registrant as specified in its charter)

Ohio	31-0958666
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
7000 Cardinal Place Dublin , Ohio	**43017**
(Address of principal executive offices)	*(Zip Code)*

(614) 757-5000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common shares (without par value)	**CAH**	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☑

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of voting stock held by non-affiliates on December 31, 2023, was the following: $24,413,491,673.

The number of the registrant's common shares, without par value, outstanding as of July 31, 2024, was the following: 243,845,343.

Documents Incorporated by Reference:

Portions of the registrant's Definitive Proxy Statement to be filed for its 2024 Annual Meeting of Shareholders are incorporated by reference into the sections of this Form 10-K addressing the requirements of Part III of Form 10-K.

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Introduction

References to Cardinal Health and Fiscal Years

As used in this report, "we," "our," "us," "Cardinal Health" and similar pronouns refer to Cardinal Health, Inc. and its majority-owned and consolidated subsidiaries, unless the context requires otherwise. Our fiscal year ends on June 30. References to fiscal 2025, 2024, 2023, 2022, 2021 and 2020 are to the fiscal years ended June 30, 2025, 2024, 2023, 2022, 2021 and 2020, respectively. Except as otherwise specified, information in this report is provided as of June 30, 2024.

Non-GAAP Financial Measures

In this report, we use financial measures that are derived from consolidated financial data but are not presented in our financial statements that are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). These measures are considered "non-GAAP financial measures" under the Securities and Exchange Commission ("SEC") rules. The reasons we use these non-GAAP financial measures and the reconciliations to their most directly comparable GAAP financial measures are included in the "Explanation and Reconciliation of Non-GAAP Financial Measures" section following MD&A in this report.

Management's Discussion and Analysis ("MD&A") of Financial Condition and Results of Operations

Our MD&A within this Form 10-K generally discusses fiscal 2024 and fiscal 2023 items and year-over-year comparisons between fiscal 2024 and fiscal 2023. This Form 10-K also includes fiscal 2022 items and discussions of year-over-year comparisons between fiscal 2023 and fiscal 2022. The periods discussed in this Form 10-K have been revised herein to correct an error identified during the preparation of this Form 10-K, as well as to correct other unrelated immaterial errors. The revisions ensure comparability across all periods reflected herein. Please refer to Note 1 of the "Notes to the Consolidated Financial Statements" for additional information about these corrections.

Important Information Regarding Forward-Looking Statements

This report (including information incorporated by reference) includes forward-looking statements addressing expectations, prospects, estimates and other matters that are dependent upon future events or developments. Many forward-looking statements appear in MD&A and Risk Factors, but there are others throughout this report, which may be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "will," "should," "could," "would," "project," "continue," "likely," and similar expressions, and include statements reflecting future results or guidance, statements of outlook and expense accruals. These matters are subject to risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied. The most significant of these risks and uncertainties are described in "Risk Factors" in this report and in Exhibit 99.1 to the Form 10-K included in this report. Forward-looking statements in this report speak only as of the date of this document. Except to the extent required by applicable law, we undertake no obligation to update or revise any forward-looking statement.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports are available free of charge on our website (www.cardinalhealth.com), under the "Investor Relations — Financial Reporting — SEC Filings" caption, as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. The SEC also maintains a website (www.sec.gov) where you can search for annual, quarterly and current reports, proxy and information statements and other information regarding us and other public companies.

Management's Discussion and Analysis of Financial Condition and Results of Operations

About Cardinal Health

Cardinal Health, Inc., an Ohio corporation formed in 1979, is a global healthcare services and products company providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories, physician offices and patients in the home. We provide pharmaceuticals and medical products and cost-effective solutions that enhance supply chain efficiency. We connect patients, providers, payers, pharmacists and manufacturers for integrated care coordination.

Effective January 1, 2024, we began operating under an updated organizational structure and re-aligned our financial reporting structure under two reportable segments: Pharmaceutical and Specialty Solutions ("Pharma") segment and Global Medical Products and Distribution ("GMPD") segment. All remaining operating segments that are not significant enough to require separate reportable segment disclosures are included in Other, which is comprised of Nuclear and Precision Health Solutions, at-Home Solutions and OptiFreight® Logistics.

Pharmaceutical and Specialty Solutions Segment

Our Pharmaceutical and Specialty Solutions segment distributes branded and generic pharmaceutical, specialty pharmaceutical and over-the-counter healthcare and consumer products in the United States. This segment also provides services to pharmaceutical manufacturers and healthcare providers for specialty pharmaceutical products; provides pharmacy management services to hospitals and operates a limited number of pharmacies, including pharmacies in community health centers; and repackages generic pharmaceuticals and over-the-counter healthcare products.

Global Medical Products and Distribution Segment

Our GMPD segment manufactures, sources and distributes Cardinal Health brand medical, surgical and laboratory products, which are sold in the United States, Canada, Europe, Asia and other markets. In addition to distributing Cardinal Health brand products, this segment also distributes a broad range of medical, surgical and laboratory products known as national brand products to hospitals, ambulatory surgery centers, clinical laboratories and other healthcare providers in the United States and Canada.

Consolidated Results

In connection with the preparation of our Consolidated Financial Statements for fiscal 2024, we identified an accounting error related to revenue recognition from third party payors within the at-Home Solutions operating segment. We evaluated the materiality of the error and determined that the impacts were not material, individually or in the aggregate, to our previously issued Consolidated Financial Statements for any of the prior quarters or annual periods in which they occurred. In this report, we present revised prior period financial statements to correct this error, as well as other unrelated immaterial errors, including an adjustment to an uncertain tax position. These other immaterial errors were previously corrected in the periods they were identified; however, they are now reflected in the periods they originated. The revisions ensure comparability across all periods reflected herein. Refer to Note 1 of the "Notes to Consolidated Financial Statements" for additional information regarding the immaterial corrections to our results of prior periods.

Overview

Revenue

Revenue increased 11 percent to $226.8 billion for fiscal 2024 and 13 percent to $205.0 billion for fiscal 2023 compared to their respective prior-year periods, primarily due to branded and specialty pharmaceutical sales growth from existing customers.

GAAP and Non-GAAP Operating Earnings/(Loss)

	GAAP and Non-GAAP Operating Earnings/(Loss)			Change	
(in millions)	2024	2023	2022	2024	2023
GAAP operating earnings/(loss)	**$ 1,243**	$ 752	$ (607)	**65 %**	N.M.
State opioid assessment related to prior fiscal years	**—**	(6)	—		
Shareholder cooperation agreement costs	**1**	8	—		
Restructuring and employee severance	**175**	95	101		
Amortization and other acquisition-related costs	**284**	285	324		
Impairments and (gain)/loss on disposal of assets, net	**634**	1,246	2,060		
Litigation (recoveries)/charges, net	**78**	(304)	94		
Non-GAAP operating earnings	**$ 2,414**	$ 2,076	$ 1,973	**16 %**	5 %

The sum of the components and certain computations may reflect rounding adjustments.

We had GAAP operating earnings of $1.2 billion and $752 million during fiscal 2024 and 2023, respectively, which included $675 million and $1.2 billion pre-tax non-cash goodwill impairment charges related to the GMPD segment. See the "Critical Accounting Policies and Sensitive Accounting Estimates" section of this MD&A and Note 5 of the "Notes to Consolidated Financial Statements" for additional detail.

GAAP operating earnings during fiscal 2023 were favorably impacted by litigation recoveries as described further in the "Results of Operations" section of this MD&A and Note 8 of the "Notes to Consolidated Financial Statements."

We had a GAAP operating loss of $607 million during fiscal 2022, which included $2.1 billion pre-tax non-cash goodwill impairment charges related to the GMPD segment. See the "Critical Accounting Policies and Sensitive Accounting Estimates" section of this MD&A and Note 5 of the "Notes to Consolidated Financial Statements" for additional detail.

GAAP and Non-GAAP operating earnings increased during fiscal 2024, driven by increases in GMPD and Pharmaceutical and Specialty Solutions segment profit as described further in the "Results of Operations" section of this MD&A.

Non-GAAP operating earnings increased during fiscal 2023, driven by an increase in Pharmaceutical and Specialty Solutions segment profit, partially offset by a decrease in GMPD segment profit as described further in the "Results of Operations" section of this MD&A.

GAAP and Non-GAAP Diluted EPS

($ per share)	GAAP and Non-GAAP diluted EPS 2024 [2]	2023 [2]	2022 [2][3]	Change 2024	2023
GAAP diluted EPS [1]	**$ 3.45**	$ 1.26	$ (3.37)	**N.M.**	N.M.
State opioid assessment related to prior fiscal years	**—**	(0.02)	—		
Shareholder cooperation agreement costs	**—**	0.02	—		
Restructuring and employee severance	**0.54**	0.28	0.27		
Amortization and other acquisition-related costs	**0.85**	0.80	0.87		
Impairments and (gain)/loss on disposal of assets, net [4]	**2.38**	4.35	7.03		
Litigation (recoveries)/charges, net	**0.30**	(0.84)	0.28		
Loss on early extinguishment of debt	**—**	—	0.03		
Non-GAAP diluted EPS [1]	**$ 7.53**	$ 5.85	$ 5.07	**29 %**	15 %

The sum of the components and certain computations may reflect rounding adjustments.

(1) Diluted earnings/(loss) per share attributable to Cardinal Health, Inc. ("diluted EPS" or "diluted loss per share").

(2) The reconciling items are presented within this table net of tax. See quantification of tax effect of each reconciling item in our GAAP to Non-GAAP Reconciliations in the section titled "Explanation and Reconciliation of Non-GAAP Financial Measures."

(3) For fiscal 2022, GAAP diluted loss per share attributable to Cardinal Health, Inc. and the EPS impact from the GAAP to non-GAAP per share reconciling items are calculated using a weighted average of 279 million common shares, which excludes potentially dilutive securities from the denominator due to their anti-dilutive effects resulting from our GAAP net loss for the period. Fiscal 2022 non-GAAP diluted EPS is calculated using a weighted average of 280 million common shares, which includes potentially dilutive shares.

(4) For fiscal 2024, 2023 and 2022, impairments and (gain)/loss on disposals of assets, net includes pre-tax goodwill impairment charges of $675 million, $1.2 billion and $2.1 billion related to the GMPD segment, respectively. For fiscal 2024, 2023 and 2022, the net tax benefit related to these charges was $58 million, $92 million and $140 million, respectively, and were included in the annual effective tax rate.

The increases in fiscal 2024 and 2023 GAAP diluted EPS were primarily due to the factors impacting GAAP operating earnings. During fiscal 2024, 2023 and 2022, GAAP diluted EPS was adversely impacted by the goodwill impairment charges related to the GMPD segment, which had $(2.50), $(4.33) and $(6.97) per share after-tax impacts, respectively. See the "Critical Accounting Policies and Sensitive Accounting Estimates" section of this MD&A and Note 5 and Note 9 of the "Notes to Consolidated Financial Statements" for additional detail.

During fiscal 2024, non-GAAP diluted EPS increased 29 percent to $7.53 due to the factors impacting non-GAAP operating earnings described above and a lower share count.

During fiscal 2023, non-GAAP diluted EPS increased 15 percent to $5.85 due to a lower share count, the factors impacting non-GAAP operating earnings described above and lower interest expense, net.

Cash and Equivalents

Our cash and equivalents balance was $5.1 billion at June 30, 2024 compared to $4.1 billion at June 30, 2023. During fiscal 2024, net cash provided by operating activities was $3.8 billion, which includes the impact of our annual payment of $378 million and prepayments of $239 million primarily related to the agreement to settle the vast majority of the opioid lawsuits filed by states and local governmental entities (the "National Opioid Settlement Agreement"). During fiscal 2024, we issued additional long-term debt and received net proceeds of $1.14 billion, of which $200 million is invested in short-term time deposits with initial effective maturities of more than three months and classified as prepaid expenses and other in our consolidated balance sheet as of June 30, 2024. In addition, during fiscal 2024 we deployed $1.2 billion for the Specialty Networks acquisition, $783 million for debt repayments, $750 million for share repurchases, $511 million for capital expenditures and $499 million for cash dividends.

Our cash and equivalents balance was $4.1 billion at June 30, 2023 compared to $4.7 billion at June 30, 2022. During fiscal 2023, net cash provided by operating activities was $2.8 billion, which was offset by $2.0 billion for share repurchases, $579 million for debt repayments, $525 million for cash dividends and $481 million for capital expenditures.

Significant Developments in Fiscal 2024 and Trends

Operating and Segment Reporting Structure Changes

Effective January 1, 2024, we began operating under an updated organizational structure and re-aligned our financial reporting structure under two reportable segments: Pharmaceutical and Specialty Solutions segment and GMPD segment. All remaining operating segments that are not significant enough to require separate reportable segment disclosures are included in Other. The following indicates the changes from the second quarter of fiscal 2024 to the new reporting structure:

- Pharmaceutical and Specialty Solutions segment: This reportable segment is comprised of all businesses formerly within our Pharmaceutical segment except Nuclear and Precision Health Solutions.
- GMPD segment: This reportable segment is comprised of all businesses formerly within our Medical segment except at-Home Solutions and OptiFreight® Logistics.
- Other: This is comprised of the remaining operating segments, Nuclear and Precision Health Solutions, at-Home Solutions and OptiFreight® Logistics.

Our previously reported segment results have been recast to conform to our new reporting structure and reflect changes in the elimination of inter-segment revenue and allocated corporate technology and shared function expenses, which are driven by the reporting structure change.

Pharmaceutical and Specialty Solutions Segment

OptumRx Contracts

On April 22, 2024, we announced that our pharmaceutical distribution contracts with OptumRx would expire at the end of June 2024. Sales to OptumRx generated 17 percent of our consolidated revenue in fiscal 2024; however, due to the class of trade, sales to OptumRx generated a meaningfully lower operating margin than the overall Pharmaceutical and Specialty Solutions segment. We expect the expiration of the OptumRx contracts to adversely impact our results of operations, including segment profit, financial condition and cash flows in fiscal 2025. In particular, we expect the unwinding of the negative net working capital associated with the contract to negatively impact operating cash flow in fiscal 2025.

Specialty Networks Acquisition

On March 18, 2024, we completed the acquisition of Specialty Networks for a purchase price of $1.2 billion in cash, subject to certain adjustments. Specialty Networks creates clinical and economic value for independent specialty providers and partners across multiple specialty group purchasing organizations ("GPOs"): UroGPO, Gastrologix and GastroGPO, and United Rheumatology. Specialty Networks' PPS Analytics platform analyzes data from electronic medical records, practice management, imaging, and dispensing systems and transforms it into meaningful and actionable insights for providers and other stakeholders by using artificial intelligence and modern data analytics capabilities. The acquisition further expands our offerings in key therapeutic areas, accelerates our upstream data and research opportunities with biopharma manufacturers, and creates a platform for our expansion across therapeutic areas. We expect the Specialty Networks acquisition to positively impact Pharmaceutical and Specialty Solutions segment revenue and profit while increasing amortization and other acquisition-related costs during fiscal 2025 and beyond.

Branded Pharmaceuticals

During fiscal 2024, we saw increased demand for GLP-1 pharmaceuticals, and our sales increased significantly, despite periodic supply shortages. These increased sales positively impacted our Pharmaceutical segment and consolidated revenue for the year; however, GLP-1 sales did not meaningfully contribute to segment profit. Future demand for these medications is unpredictable and our ability to meet demand may be impacted by additional supply constraints.

During fiscal 2024, we began distributing commercially available COVID-19 vaccines following U.S. Food and Drug Administration ("FDA") approval. Distribution of these vaccines had a greater than anticipated benefit to Pharmaceutical and Specialty Solutions segment profit in fiscal year 2024. Updated COVID-19 vaccines for 2025 also require FDA approval. We expect COVID-19 vaccine distribution to favorably impact Pharmaceutical and Specialty Solutions segment profit in fiscal 2025, but to a lesser extent.

Generics Program

The performance of our Pharmaceutical and Specialty Solutions segment generics program positively impacted the year-over-year comparison of Pharmaceutical and Specialty Solutions segment profit. The Pharmaceutical and Specialty Solutions segment generics program includes, among other things, the impact of generic pharmaceutical product launches, customer volumes, pricing changes, the Red Oak Sourcing, LLC venture ("Red Oak Sourcing") with CVS Health Corporation ("CVS Health") and generic pharmaceutical contract manufacturing and sourcing costs.

The frequency, timing, magnitude and profit impact of generic pharmaceutical customer volumes, pricing changes, customer contract renewals, generic pharmaceutical manufacturer pricing changes and generic pharmaceutical contract manufacturing and sourcing costs all impact Pharmaceutical and Specialty Solutions segment profit and are subject to risks and uncertainties. These risks and uncertainties may impact Pharmaceutical and Specialty Solutions segment profit and consolidated operating earnings during fiscal 2025 and beyond.

Global Medical Products and Distribution Segment

Inflationary Impacts

Beginning in fiscal 2022, GMPD segment profit was negatively affected by incremental inflationary impacts, primarily related to transportation (including ocean and domestic freight), commodities and labor, and global supply chain constraints. Since that time, we have taken actions to partially mitigate these impacts, including implementing certain price increases and evolving our pricing and commercial contracting processes to provide us with greater pricing flexibility. In addition, decreases in some product-related costs have been recognized as the higher-cost inventory moved through our supply chain and was replaced by lower-cost inventory. These net inflationary impacts negatively affected GMPD segment profit during fiscal 2023. The net inflationary impacts were less significant during fiscal 2024 and had a favorable impact on GMPD segment profit on a year-over-year basis.

We expect these inflationary impacts to continue to affect GMPD segment profit in fiscal 2025 and beyond, but we expect that they will be substantially offset due to our mitigation actions. However, these inflationary costs are difficult to predict and may be greater than we expect or continue longer than our current expectations. Our actions to increase prices and evolve our contracting strategies are subject to contingencies and uncertainties and it is possible that our results of operations will be adversely impacted to a greater extent than we currently anticipate or that we may not be able to mitigate the negative impact to the extent or on the timeline we anticipate.

Volumes

GMPD segment profit was adversely impacted during fiscal 2023 in part due to lower volumes, which included our Cardinal Health brand medical products. We experienced Cardinal Health brand medical products sales growth during fiscal 2024 and expect further growth in fiscal 2025 and beyond. The timing, magnitude and profit impact of this anticipated sales growth is subject to risks and uncertainties, which may impact GMPD segment profit.

Goodwill

The change in segment structure as discussed above resulted in changes to the composition of our reporting units. Accordingly, we were required to reallocate the goodwill in reporting units affected by the change using a relative fair value approach and assess goodwill for impairment both before and after the reallocation. During the three months ended March 31, 2024, we allocated $90 million and $48 million of goodwill from the former Medical segment excluding our at-Home Solutions division (the "Medical Unit") to the GMPD reporting unit and the OptiFreight® Logistics reporting unit, respectively. We also assessed GMPD's goodwill for impairment and determined there was an impairment of GMPD's remaining goodwill balance of $90 million, resulting in GMPD goodwill being fully impaired. See the "Critical Accounting Policies and Sensitive Accounting Estimates" section of this MD&A and Note 5 of the "Notes to Consolidated Financial Statements" for additional detail.

Shareholder Cooperation Agreement

In September 2022, we entered into a Cooperation Agreement (the "Cooperation Agreement") with Elliott Associates, L.P. and Elliott International, L.P. (together, "Elliott") under which our Board of Directors (the "Board"), among other things, (1) appointed four new independent directors, including a representative from Elliott, and (2) formed an advisory Business Review Committee of the Board tasked with undertaking a comprehensive review of our strategy, portfolio, capital-allocation framework and operations. In May 2023, we extended the term of the Cooperation Agreement until the later of July 15, 2024 or until Elliott's representative ceases to serve on, or resigns from, the Board. In connection with this extension, the Board extended the term of the Business Review Committee until July 15, 2024. On that date, the Business Review Committee disbanded in accordance with its charter. The Cooperation Agreement remains in effect.

The evaluation and implementation of actions recommended by the Business Review Committee and the Board have impacted and may continue to impact our business, financial position and results of operations during fiscal 2025 and beyond. During fiscal 2024 and 2023, we incurred $1 million and $8 million of expenses related to the negotiation and finalization of the Cooperation Agreement and other consulting expenses, respectively. We have incurred, and may incur additional legal, consulting and other expenses related to the Cooperation Agreement.

Results of Operations

Revenue

(in millions)	Revenue 2024	2023	2022	Change 2024	2023
Pharmaceutical and Specialty Solutions	$ 210,019	$ 188,814	$ 164,596	11 %	15 %
Global Medical Products and Distribution	12,381	12,222	13,280	1 %	(8)%
Other	4,512	4,021	3,518	12 %	14 %
Total segment revenue	226,912	205,057	181,394	11 %	13 %
Corporate [1]	(85)	(78)	(68)	N.M.	N.M.
Total revenue	$ 226,827	$ 204,979	$ 181,326	11 %	13 %

(1) Corporate revenue consists of the elimination of inter-segment revenue and other revenue not allocated to the segments.

Fiscal 2024 Compared to Fiscal 2023

Pharmaceutical and Specialty Solutions

Fiscal 2024 Pharmaceutical and Specialty Solutions segment revenue grew by 11 percent primarily due to branded and specialty pharmaceutical sales growth largely from existing customers, which increased revenue by $20.1 billion.

Global Medical Products and Distribution

Fiscal 2024 GMPD segment revenue increased primarily due to higher volumes from existing customers, which increased revenue by $275 million. The increase was partially offset by the adverse impact of personal protective equipment ("PPE") pricing.

Other

Fiscal 2024 Other revenue increased due to growth across the at-Home Solutions, Nuclear and Precision Health Solutions and OptiFreight® Logistics operating segments.

Fiscal 2023 Compared to Fiscal 2022

Pharmaceutical and Specialty Solutions

Fiscal 2023 Pharmaceutical and Specialty Solutions segment revenue grew by 15 percent primarily due to branded and specialty pharmaceutical sales growth from existing and net new customers, which increased revenue by $24.2 billion.

Global Medical Products and Distribution

Fiscal 2023 GMPD segment revenue decreased primarily due to lower sales, largely due to an adverse impact of PPE pricing and volumes.

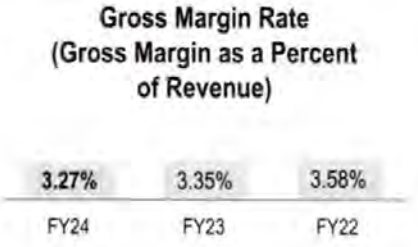
Other

Fiscal 2023 Other revenue increased due to growth across the Nuclear and Precision Health Solutions, at-Home Solutions and OptiFreight® Logistics operating segments.

Cost of Products Sold

Cost of products sold for fiscal 2024 and 2023 increased $21.3 billion (11 percent) and $23.3 billion (13 percent) compared to their respective prior-year periods as a result of the same factors affecting the changes in revenue and gross margin.

Gross Margin



(in millions)	Consolidated Gross Margin 2024	2023	2022	Change 2024	2023
Gross margin	$ 7,414	$ 6,874	$ 6,484	8 %	6 %

Fiscal 2024 Compared to Fiscal 2023

Fiscal 2024 consolidated gross margin increased primarily due to the beneficial comparison of the prior-year net inflationary impacts in the GMPD segment and the positive performance of our generics program in the Pharmaceutical and Specialty Solutions segment.

Gross margin rate declined 8 basis points during fiscal 2024 mainly due to changes in overall product mix, primarily driven by increased pharmaceutical distribution branded sales, which have a dilutive impact on our overall gross margin rate. This decline in gross margin rate was partially offset by the beneficial comparison to the prior-year net inflationary impacts in the GMPD segment.

Fiscal 2023 Compared to Fiscal 2022

Fiscal 2023 consolidated gross margin increased primarily due to the Pharmaceutical and Specialty Solutions segment, which reflected the positive performance of our generics program and a higher contribution from branded and specialty pharmaceutical products. This increase was partially offset by the GMPD segment, primarily driven by lower volumes and unfavorable product sales mix, partially offset by a net positive contribution from PPE.

Gross margin rate declined 23 basis points during fiscal 2023 mainly due to changes in overall product mix, primarily driven by increased pharmaceutical distribution branded sales, which have a dilutive impact on our overall gross margin rate. This decline in gross margin rate was partially offset by a net positive contribution from PPE.

Distribution, Selling, General and Administrative ("SG&A") Expenses

(in millions)	SG&A Expenses			Change	
	2024	2023	2022	2024	2023
SG&A expenses	$ 5,000	$ 4,800	$ 4,512	4 %	6 %

Fiscal 2024 Compared to Fiscal 2023

Fiscal 2024 SG&A expenses increased primarily due to compensation related costs, investment projects and higher costs to support sales growth. These increases were partially offset by the beneficial impact of enterprise-wide cost-savings measures.

Fiscal 2023 Compared to Fiscal 2022

Fiscal 2023 SG&A expenses increased primarily due to higher costs to support sales growth, compensation related costs and inflationary impacts. These increases were partially offset by the beneficial impact of enterprise-wide cost-savings measures.

Segment Profit

We evaluate segment performance based on segment profit, among other measures. See Note 14 of the "Notes to Consolidated Financial Statements" for additional information on segment profit.

(in millions)	Segment Profit and Operating Earnings/(Loss)			Change	
	2024	2023	2022	2024	2023
Pharmaceutical and Specialty Solutions	$ 2,015	$ 1,881	$ 1,643	7 %	14 %
Global Medical Products and Distribution	92	(147)	(64)	N.M.	N.M.
Other	423	396	390	7 %	2 %
Total segment profit	2,530	2,130	1,969	19 %	8 %
Corporate	(1,287)	(1,378)	(2,576)	N.M.	N.M.
Total consolidated operating earnings/(loss)	$ 1,243	$ 752	$ (607)	65 %	N.M.

Fiscal 2024 Compared to Fiscal 2023

Pharmaceutical and Specialty Solutions

Fiscal 2024 Pharmaceutical and Specialty Solutions segment profit increased primarily due to the positive performance of our generics program.

Global Medical Products and Distribution

Fiscal 2024 GMPD segment profit increased primarily due to the beneficial comparison to the prior-year inflationary impacts, net of the effects of mitigation actions.

Other

Fiscal 2024 Other segment profit increased primarily due to the performance of OptiFreight® Logistics.

Corporate

The changes in Corporate during fiscal 2024 are due to the factors discussed in the "Other Components of Consolidated Operating Earnings/(Loss)" section that follows.

Fiscal 2023 Compared to Fiscal 2022

Pharmaceutical and Specialty Solutions

Fiscal 2023 Pharmaceutical and Specialty Solutions segment profit increased primarily due to the positive performance of our generics program and an increased contribution from branded and specialty pharmaceutical products, partially offset by inflationary impacts, primarily related to increased transportation and labor costs.

Global Medical Products and Distribution

Fiscal 2023 GMPD segment profit decreased primarily due to net inflationary impacts, lower volumes and unfavorable product sales mix, partially offset by a net positive contribution from PPE.

Other

Fiscal 2023 Other segment profit increased primarily due to the performance of OptiFreight® Logistics.

Corporate

The changes in Corporate during fiscal 2023 are due to the factors discussed in the "Other Components of Consolidated Operating Earnings/(Loss)" section that follows.

Other Components of Consolidated Operating Earnings/(Loss)

In addition to revenue, gross margin and SG&A expenses discussed previously, consolidated operating earnings/(loss) were impacted by the following:

(in millions)	2024	2023	2022
Restructuring and employee severance	$ 175	$ 95	$ 101
Amortization and other acquisition-related costs	284	285	324
Impairments and (gain)/loss on disposal of assets, net	634	1,246	2,060
Litigation (recoveries)/charges, net	78	(304)	94

Restructuring and Employee Severance

Restructuring and employee severance costs in fiscal 2024, 2023 and 2022 include costs related to the implementation of certain enterprise-wide cost-savings measures, which include certain initiatives to rationalize our manufacturing operations. The increase in fiscal 2024 restructuring costs are primarily due to estimated severance costs related to these cost-savings measures and costs related to certain projects resulting from the reviews of our strategy, portfolio, capital-allocation framework and operations. During fiscal 2023 and 2022, restructuring and employee severance included costs related to the divestiture of the Cordis business. During fiscal 2022, restructuring also included facility-exit costs related to decreasing our overall office space.

Amortization and Other Acquisition-Related Costs

Amortization of acquisition-related intangible assets was $264 million, $281 million and $311 million for fiscal 2024, 2023 and 2022, respectively.

Impairments and (Gain)/Loss on Disposal of Assets, Net

During fiscal 2024, 2023 and 2022, we recognized $675 million, $1.2 billion and $2.1 billion of pre-tax non-cash goodwill impairment charges, respectively, related to our GMPD segment, as discussed further in the "Critical Accounting Policies and Sensitive Accounting Estimates" section of this MD&A and Note 5 of the "Notes to Consolidated Financial Statements."

Litigation (Recoveries)/Charges, Net

During fiscal 2024, we recognized expense of $340 million in connection with opioid-related matters, including agreements in principle with counsel representing classes of third-party payors and acute care hospitals, the case brought by the City of Baltimore, and a settlement with the State of Alabama. This expense was partially offset by a benefit of $105 million related to certain prepayments and $34 million in insurance recoveries. We also recognized income of $117 million for net recoveries in class action lawsuits in which we were a class member or plaintiff.

During fiscal 2023, we recognized income of $130 million for net recoveries in class action lawsuits in which we were a class member or plaintiff. We recognized income of $103 million primarily related to a reduction of the reserve for the estimated settlement and defense costs for the Cordis OptEase and TrapEase inferior vena cava ("IVC") product liability due to the execution of certain settlement agreements. We also recognized income of $93 million due to net proceeds from the settlement of a shareholder derivative litigation matter.

During fiscal 2022, we recognized estimated losses and legal defense costs associated with the IVC filter product liability claims of $70 million. We also recognized income of $18 million for net recoveries in class action antitrust lawsuits in which we were a class member or plaintiff.

See Note 8 of the "Notes to Consolidated Financial Statements" for additional information.

Other Components of Earnings/(Loss) Before Income Taxes

In addition to the items discussed above, earnings/(loss) before income taxes was impacted by the following:

(in millions)	Earnings/(loss) Before Income Taxes			Change	
	2024	2023	2022	2024	2023
Other (income)/expense, net	$ (9)	$ 5	$ 22	N.M.	N.M.
Interest expense, net	51	84	147	(39)%	(43)%
Loss on early extinguishment of debt	—	—	10	N.M.	N.M.
(Gain)/Loss on sale of equity interest in naviHealth	—	—	(2)	N.M.	N.M.

Interest Expense, Net

Fiscal 2024 and 2023 interest expense, net decreased primarily due to increased interest income from cash and equivalents. The decrease in Fiscal 2024 interest expense, net was partially offset by lower interest income from financial instruments.

Loss On Early Extinguishment of Debt

During fiscal 2022, we recognized a loss of $10 million in connection with the debt redemption as described further in Note 7 of the "Notes to Consolidated Financial Statements."

Provision for Income Taxes

Fluctuations in the effective tax rates are primarily due to the impact of the goodwill impairment charges recognized in fiscal 2024, 2023 and 2022 related to the GMPD segment.

A reconciliation of the provision based on the federal statutory income tax rate to our effective income tax rate from continuing operations is as follows (see Note 9 of the "Notes to Consolidated Financial Statements" for additional information):

	2024 [1]	2023 [1]	2022 [1]
Provision at Federal statutory rate	21.0 %	21.0 %	21.0 %
State and local income taxes, net of federal benefit	3.1	6.5	2.0
Tax effect of foreign operations	(1.6)	(5.4)	4.7
Nondeductible/nontaxable items	(0.1)	(1.1)	1.2
Impact of Divestitures	—	(1.9)	(4.8)
Withholding Taxes	1.0	1.0	(1.1)
Change in Valuation Allowances	(1.1)	(5.1)	3.5
US Taxes on International Income [2]	(2.1)	0.6	1.9
Impact of Resolutions with IRS and other related matters	0.4	0.3	1.6
Opioid litigation	1.0	0.1	(0.5)
Goodwill Impairment	8.7	33.8	(49.9)
Other	(1.4)	0.2	0.9
Effective income tax rate	28.9 %	50.0 %	(19.5)%

(1) This table reflects fiscal 2024 and 2023 pretax income with tax expense and fiscal 2022 pretax loss with tax expense.

(2) Includes the tax impact of Global Intangible Low-Taxed Income ("GILTI") tax, the Foreign-Derived Intangible Income deduction and other foreign income that is taxable under the U.S. tax code.

During fiscal 2024, 2023, and 2022, the effective tax rate was 28.9 percent, 50.0 percent and (19.5) percent, respectively. Included in the effective tax rate for fiscal 2024, 2023, and 2022, was $58 million, $92 million and $140 million, respectively, of benefit related to the goodwill impairment charges related to GMPD.

Ongoing Audits

We file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and various foreign jurisdictions. With few exceptions, we are subject to audit by taxing authorities for fiscal 2015 through the current fiscal year. Tax laws are complex and subject to varying interpretations. New challenges related to future audits may adversely affect our effective tax rate or tax payments.

Liquidity and Capital Resources

We currently believe that, based on available capital resources and projected operating cash flow, we have adequate capital resources to fund our operations and expected future cash needs as described below. If we decide to engage in one or more acquisitions, depending on the size and timing of such transactions, we may need to access capital markets for additional financing.

Cash and Equivalents

Our cash and equivalents balance was $5.1 billion at June 30, 2024 compared to $4.1 billion at June 30, 2023.

During fiscal 2024, net cash provided by operating activities was $3.8 billion, which includes the impact of our annual payment of $378 million and prepayments of $239 million primarily related to the National Opioid Settlement Agreement. During fiscal 2024, we issued additional long-term debt and received net proceeds of $1.14 billion, of which $200 million is invested in short-term time deposits with initial effective maturities of more than three months and classified as prepaid expenses and other in our consolidated balance sheet as of June 30, 2024. In addition, we deployed cash of $783 million for debt repayments, $750 million for share repurchases, $511 million for capital expenditures and $499 million for cash dividends. At June 30, 2024, our cash and equivalents were held in cash depository accounts with major banks or invested in high quality, short-term liquid investments.

On March 18, 2024, we completed the acquisition of Specialty Networks for a purchase price of $1.2 billion in cash, subject to certain adjustments. See Note 2 of the "Notes to Consolidated Financial Statements" for additional information.

At June 30, 2023, our cash and equivalents were $4.1 billion. During fiscal 2023, net cash provided by operating activities was $2.8 billion, which includes the impact of our second annual payment of $372 million related to the National Opioid Settlement Agreement. In addition, we deployed $2.0 billion for share repurchases, $579 million for debt repayments, $525 million for cash dividends and $481 million for capital expenditures.

Changes in working capital, which impact operating cash flow, can vary significantly depending on factors such as the timing of customer payments, inventory purchases, payments to vendors and tax payments in the regular course of business, as well as fluctuating working capital needs driven by customer and product mix. We expect the unwinding of the negative net working capital associated with the OptumRx contract to negatively impact operating cash flow in fiscal 2025.

The cash and equivalents balance at June 30, 2024 includes $497 million of cash and equivalents held by subsidiaries outside of the United States.

In fiscal 2024, we returned $384 million of cash held by foreign subsidiaries to the United States.

At June 30, 2024, foreign earnings of approximately $1.0 billion are considered indefinitely reinvested for working capital and other offshore investment needs. The computation of tax required if those earnings are repatriated is not practicable. For amounts not considered indefinitely reinvested, we have recorded an immaterial amount of income tax expense in our consolidated financial statements in fiscal 2024.

Other Financing Arrangements and Financial Instruments

Credit Facilities and Commercial Paper

In addition to cash and equivalents and operating cash flow, other sources of liquidity at June 30, 2024 include a $2.0 billion commercial paper program, backed by a $2.0 billion revolving credit facility. We also have a $1.0 billion committed receivables sales facility. At June 30, 2024, we had no amounts outstanding under our commercial paper program, revolving credit facility or our committed receivables sales facility. During fiscal 2024, under our commercial paper program and our committed receivables program, we had maximum combined total daily amounts outstanding of $1.3 billion.

In February 2023, we extended our revolving credit facility through February 25, 2028. In September 2022, we renewed our committed receivables sales facility program through Cardinal Health Funding, LLC ("CHF") through September 30, 2025. In September 2023, Cardinal Health 23 Funding, LLC was added as a seller under our committed receivables sales facility.

Our revolving credit and committed receivables sales facilities require us to maintain a consolidated net leverage ratio of no more than 3.75-to-1. As of June 30, 2024, we were in compliance with this financial covenant.

Long-Term Obligations

At June 30, 2024, we had total long-term obligations, including the current portion and other short-term borrowings of $5.1 billion.

In February 2024, we issued additional debt with the aggregate principal amount of $1.15 billion to fund the repayment of all of the aggregate principal amount outstanding of our 3.5% Notes due 2024 and 3.079% Notes due 2024, at their respective maturities, and for general corporate purposes. In June 2024, we repaid the full principal of $750 million of the 3.079% Notes due 2024. The notes issued are $650 million aggregate principal amount of 5.125% Notes that mature on February 15, 2029 and $500 million aggregate principal amount of 5.45% Notes that mature on February 15, 2034. The proceeds of the notes issued, net of discounts, premiums, and debt issuance costs were $1.14 billion. A portion of the proceeds was invested in short-term time deposits of $550 million with initial effective maturities of more than three months. At June 30, 2024, we had $200 million remaining in those

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: InfuSystem Inc.

Physical Address: 19479 Wishon Drive Suite 100

City: Bakersfield State: CA Zip: 93308

Mailing Address (if different from physical address): 3851 West Hamlin Rd

City: Rochester Hills State: MI Zip: 48309

Telephone: 800-962-9656 Website: www.infusystem.com

Name of Designated Representative (DR): Ana Luz Morando-Arellano

Licensing Company Email: jessica.younan@infusystem.com DR Email: ana.morando-arellano@infusystem.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☑ Warehouse
☑ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Long Term Care Facilities		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): _____

Corporation Name: InfuSystem Holdings Inc.

Mailing Address: 3851 West Hamlin Rd

City: Rochester Hills State: MI Zip: 48309

Telephone: 800-962-9656 Email: jessica.younan@infusystem.com

Contact Person Name: Jessica Younan

Date of SEC Registration: 03-16-2023 | SEC Registration Number: 001-35020 | Stock Exchange Symbol: INFU

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		NO
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		No
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

InfuSystem Inc.

Facility Name

Carrie Ann Lachance

Print Name of Authorized Person Submitting Application

Carrie Lachance

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

02-25-2026

Date

Board Use Only	Date Received: 3/3/25	Amount: $1000 CK 017418

CONFIDENTIAL

Directors/Officers

Name	Title	Start Date	End Date
Richard A. (Armand) Dilorio	CEO	11/15/2017	
Carrie Lachance	President/COO		
Barry Steele	EVP, CFO/Treasurer /Secretary	3/18/2020	

Owner

Full Name	Title	EIN	
Infusystem Holdings Inc.	100% Direct Ownership	20-3341405	

0

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INFUSYSTEM, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF FEBRUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "INFUSYSTEM, INC." WAS INCORPORATED ON THE TWENTY-SEVENTH DAY OF SEPTEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

2411606 8300

SR# 20240365890

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

Authentication: 202742223

Date: 02-05-24

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8516

ISSUE DATE 2/3/2025

INFUSYSTEM INC
19479 WISHON DR SUITE 100
BAKERSFIELD, CA 93308

The above is licensed with the State Board of Pharmacy as a Corporation

MORANDO ARELLANO ANA LUZ — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 2/1/2026

RECEIPT NUMBER 00771035

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

Org Level 4	Location
Warehouse	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Warehouse	Bakersfield-Office
Quality	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical, Onsite	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Procurement	Bakersfield-Office
Biomedical Services	Bakersfield-Office
Biomedical Services	Bakersfield-Office

INFUINC-01 MGREENE

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/2/2025

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

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

PRODUCER	CONTACT NAME: Michael Greene	
Alliant Insurance Services, Inc. 222 Bloomingdale Rd Ste 400 White Plains, NY 10605	PHONE (A/C, No, Ext): (914) 220-5833	FAX (A/C, No):
	E-MAIL ADDRESS: Michael.Greene@alliant.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
INSURED	INSURER A : Sompo America Insurance Company	11126
InfuSystem Inc. 3851 W Hamlin Rd Rochester Hills, MI 48309	INSURER B : Sompo America Fire & Marine Insurance Company	38997
	INSURER C : Endurance Assurance Corporation	11551
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			LGM30030366802	1/1/2025	1/1/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG **EBL AGGREGATE**	$ 2,000,000 $ 500,000 $ 15,000 $ 2,000,000 $ 2,000,000 $ Excluded $ 2,000,000
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY			LAM30031389902	1/1/2025	1/1/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			CPUS1040O0	1/1/2025	1/1/2026	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LWM30076889000	1/1/2025	1/1/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
C	Products Liability			GPM30003238100	1/1/2025	1/1/2026	Occurrence/Aggregate	5,000,000
B	Commercial Property			LPM30076826300	1/1/2025	1/1/2026	Blanket Limit	51,992,981

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Named Insureds: InfuSystem Inc.; First Biomedical, Inc.; IFC LLC, InfuSystem Holding USA, Inc.

Products/Completed Operations Liability Coverage
Includes Medical Professional Services Endorsement/Errors & Omissions
Each Occurrence Limit - $5,000,000
Aggregate Limit - $5,000,000
Professional E&O Limit - $5,000,000
SEE ATTACHED ACORD 101

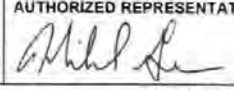
CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE



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AGENCY CUSTOMER ID: INFUINC-01 MGREENE

LOC #: 8

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Alliant Insurance Services, Inc.	InfuSystem Inc. 3851 W Hamlin Rd Rochester Hills, MI 48309
POLICY NUMBER SEE PAGE 1	
CARRIER / NAIC CODE SEE PAGE 1 / SEE P 1	EFFECTIVE DATE: SEE PAGE 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

Description of Operations/Locations/Vehicles:
SIR Per Occurrence - $25,000
SIR Aggregate - $125,000

Property: Blanket Limit - $51,992,981; Deductible - $25,000.

Additional Named Insured: InfuSystem Holdings USA, Inc, First Biomedical, Inc.; First Infusion LLC; IFC LLC

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG InfuSystem Inc. MDEG License # (if applicable) _____

Physical Address 19479 Wishon Drive Suite 100

City Bakersfield State CA Zip 93308

Mailing Address (if different from physical address) 3851 West Hamlin Rd

City Rochester Hills State MI Zip 48309

Telephone 800-962-9656 Website www.infusystem.com

Licensing Company Email jessica.younan@infusystem.com

Section 2: Personal Information

First Ana Luz Middle _____ Last Morando Arellano

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

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

Mailing Addres[redacted]

City Bakersfield State CA Zip [redacted]

Telephone 800-962-9656 Email ana.morando-arellano@infusystem.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
UEI College			11/14-08/15	
Address		**City**	**State**	**Zip**
3737 Rosedale Hwy		Bakersfield	CA	93308
Diploma/Degree obtained, if any	Pharmacy Technician Diploma			

School Name			From - To (MM/YY – MM/YY)	
California College of Vocational Careers			07/12-06/13	
Address		**City**	**State**	**Zip**
1901 Chester Ave		Bakersfield	CA	93301
Diploma/Degree obtained, if any	Medical Assistant Certificate			

School Name			From - To (MM/YY – MM/YY)	
California State University, Bakersfield			06/10-03/12	
Address		**City**	**State**	**Zip**
9001 Stockdale Hwy		Bakersfield	CA	93311
Diploma/Degree obtained, if any				

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/18- present	[redacted]	Bakersfield	CA	[redacted]
10/95-05/18		Bakersfield	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Infusystem Inc.			06/24- present
Business Address	**City**	**State**	**Zip**
19479 Wishon Drive	Bakersfield	CA	93308
Phone	**Title**	**Number of Employed Hours**	
(661)489-1759	Biomedical Technician I	1500	

Description of Duties
Checking invoices from incoming devices, arranging devices on shelves by date of maintenance, helping with technician daily duty assignments, cycle count, assisting with quality control, processing orders, and coordinating par levels.

Business Name			From - To (MM/YY – MM/YY)
Bakersfield Rehabilitation Hospital			02/23-10/24
Business Address	**City**	**State**	**Zip**
4400 Kirkcaldy Drive	Bakersfield	CA	93306
Phone	**Title**	**Number of Employed Hours**	
(661)688-7000	Pharmacy Technician II	2,850	

Description of Duties
Retrieves, counts, and measures drugs, assists Pharmacist in price-checking and restocking of drugs, accesses, inputs, and retrieves prescription information from computer, refers physicians' calls and any medical questions to pharmacist, integrates the hospital's mission and "Guiding Principles" into daily practice, cleaning IV room.

Business Name			From - To (MM/YY – MM/YY)
Kern Medical Hospital			10/20-08/22
Business Address	**City**	**State**	**Zip**
1700 Mount Vernon Avenue	Bakersfield	CA	93306
Phone	**Title**	**Number of Employed Hours**	
(661) 326-2000	Pharmacy technician	3,520	

Description of Duties
automated pharmacy equipment, maintain patient medication profiles by properly charging and crediting computer system for inpatients and outpatients, receives prescriptions from outpatients, enters data into computer system and assists pharmacist with record keeping and charging/crediting; assists in dispensing completed prescriptions to outpatients or discharge patients, fills orders using automated dispensing devises and completes basic functions, such as filling cells (outpatient), filling/removing items in MedStations (PYXIS); performs report checking/resolves discrepancies and performs basic trouble shooting, prepare sterile solutions using aseptic technique manually and with automated equipment

Business Name			From - To (MM/YY – MM/YY)
Mercy Hospital Downtown			01/21-05/21
Business Address	**City**	**State**	**Zip**
2215 Truxtun Avenue	Bakersfield	CA	93301
Phone	**Title**	**Number of Employed Hours**	
(661) 632-5000	Pharmacy Technician Per Diem	300	

Description of Duties
Responsible for performing a variety of compounding, preparing, resupplying and labeling of medications, under the direct supervision of the pharmacist. Also, responsible for performing a variety of clerical functions including answering the phone, waiting on customers, filing orders, billing, computer operating, readying medications for delivery and other related duties.

Business Name			From - To (MM/YY – MM/YY)
Bakersfield Memorial Hospital			07/18-11/19
Business Address	**City**	**State**	**Zip**
42 34th Street	Bakersfield	CA	93301
Phone	**Title**	**Number of Employed Hours**	
(661) 327-4647	Pharmacy Technician I	2,200	

Description of Duties
Performs all duties related to preparation and dispensing of medication orders, receives supplies and checks receipts against requisitions, withdraws outdated drugs, fill and troubleshoot Omnicell machine, and unit dosing.

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Ana Luz Morando-Arellano, **certify that as the MDEG Administrator for**

_____,

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

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

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

Ana Morando Arellano
Print Name (First, Last)

Ana Morando Arellano
Original Signature (electronic, copies or stamps not accepted)

02/25/2025
Date

Board Use Only	Date Received: 2/3/25

Active Directory Employee Listing

ment Stat	First Name	Preferred	Last Name	Supervisor Name
A	Cristeta	Tita	Galinato	Hafenstine, Michael
A	Mark Lyndon	Mark	Limpag	Tangeman, Alex
A	Bernardo	Bernard	Juarez	Galinato, Cristeta M.
A	Robert		Mayo	Her, Pao
A	Sergio		Areas	Limpag, Mark Lyndon T.
A	Sharl		Boutrous	Limpag, Mark Lyndon T.
A	Andres		Hernandez	Limpag, Mark Lyndon T.
A	Paul Daniel	Dan	Legrama	Limpag, Mark Lyndon T.
A	Herman	Oman	Noora	Limpag, Mark Lyndon T.
A	Edgar	Edgar	Obsioma	Limpag, Mark Lyndon T.
A	Edward		Olson	Limpag, Mark Lyndon T.
A	Mathew	Mathew	Ramirez	Morgan, Kenneth D.
A	Braion		Tria	Limpag, Mark Lyndon T.
A	Roderick	Erick	Zabat	Limpag, Mark Lyndon T.
A	Lilibeth	Beth	Jimeno	Schifsky, Lawrence R.
A	Ana	Ana	Morando Arellano	Limpag, Mark Lyndon T.
A	Estefania		Gamino	Limpag, Mark Lyndon T.

Job (Long)	Org Level 1	Org Level 2
Warehouse Facility Supervisor	Operations	Warehouse
Operations Manager	Operations	Biomedical Services
Lead Warehouse Operator	Operations	Warehouse
Quality Control Technician	Operations	Quality
Biomedical Technician III	Operations	Biomedical Services
Biomedical Technician II	Operations	Biomedical Services
Biomedical Technician I	Operations	Biomedical Services
Biomedical Technician III	Operations	Biomedical Services
Biomedical Technician III	Operations	Biomedical Services
Biomedical Technician III	Operations	Biomedical Services
Biomedical Technician III	Operations	Biomedical Services
Biomedical Onsite Technician II	Operations	Biomedical Services
Biomedical Technician II	Operations	Biomedical Services
Lead Biomedical Technician	Operations	Biomedical Services
Senior Purchasing Coordinator	Operations	Procurement
Biomedical Technician I	Operations	Biomedical Services
Biomedical Technician I	Operations	Biomedical Services

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C., 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-35020

INFUSYSTEM HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-3341405**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

3851 West Hamlin Road
Rochester Hills, Michigan 48309
(Address of Principal Executive Offices) (Zip Code)
Registrant's Telephone Number, including Area Code:
(248) 291-1210

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, par value $0.0001 per share	INFU	NYSE American LLC

Securities Registered Pursuant to Section 12(g) of the Act:
None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter periods as the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting equity held by non-affiliates of the registrant, computed by reference to the price at which the common stock was last sold as of the last business day of the registrants most recently completed second fiscal quarter, was $172,308,011. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors and officers of the registrant and persons who hold 10% or more of the outstanding common stock of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of shares of the registrant's common stock outstanding as of March 10, 2023 was 20,893,018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for its 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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References in this Form 10-K to "we", "us", or the "Company" are to InfuSystem Holdings, Inc. ("InfuSystem") and our wholly owned subsidiaries, as appropriate to the context.

Cautionary Statement About Forward-Looking Statements

Certain statements contained in this Form 10-K are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "strategy," "future," "likely," variations of such words, and other similar expressions, as they relate to the Company, are intended to identify forward-looking statements. However, the absence of these words or similar expressions does not mean that a statement is not forward-looking. In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, the Company is identifying certain factors that could cause actual results to differ, perhaps materially, from those indicated by these forward-looking statements. InfuSystem does not intend and does not undertake any obligation to update any forward-looking statement to reflect future events or circumstances after the date of such statements, except as may be required by law. Important factors that could cause our actual results and financial condition to differ materially from the forward-looking statements include, without limitation, those described in "Risk Factors" and elsewhere in this Form 10-K, and the following:

- changes in third-party reimbursement processes, rates, contractual relationships and payer mix;
- our dependence on estimates of collectible revenue from third-party reimbursement;
- risks associated with the loss of a relationship with one or more third-party payers;
- risks associated with a federal government shutdown;
- risks associated with payer concentration;
- physicians' acceptance of infusion pump therapy over alternative therapies and focus on early detection and diagnostics;
- our dependence on our Medicare Suppler Number, which allows us to bill Medicare for services provided to Medicare patients;
- availability of chemotherapy drugs used in our infusion pump systems;
- our expectations regarding enacted and potential legislative and regulatory changes impacting, among other things, the level of reimbursement received from the Medicare and state Medicaid programs including the Center for Medicare and Medicaid Services ("CMS") competitive bidding;
- our dependence upon our suppliers;
- periodic reviews and billing audits from governmental and private payers;
- our ability to maintain controls and processes over billing and collection and the adequacy of our allowance for doubtful accounts and customer concessions;
- our ability to comply with state licensure laws for Durable Medical Equipment suppliers;
- risks associated with our allowance for doubtful accounts and customer concessions;
- our ability to execute our business strategies to grow our business, including our ability to introduce new products and services;
- industry competition;
- compliance with regulatory guidelines affecting our billing practices;
- defective products manufactured by third-party suppliers;
- our ability to execute on acquisition and joint-venture opportunities and integrate any acquired businesses;
- our ability to maintain relationships with health care professionals and organizations;
- our ability to comply with changing health care regulations;
- our ability to protect our intellectual property;
- our ability to remain in compliance with our credit agreement or future debt agreements;
- general economic uncertainty;
- changes in tax laws or challenges to our tax positions;
- the value of our net operating loss carryforwards may become impaired if we do not generate sufficient future taxable income required to utilize all or a portion of our net operating loss carryforwards prior to their expiration;
- volatility in the market price of our stock;
- the future price of our stock may be negatively affected by not paying dividends;
- potential dilution to current stockholders from the issuance of equity awards;
- we may be subject to limitations on net operating loss carryforwards and certain built-in losses following an ownership change;
- our ability to remediate the material weaknesses in our internal control over financial reporting;
- the long-term effects of the coronavirus ("COVID-19") pandemic, or any other global pandemic or disease outbreak, on our business;

- litigation or other legal or regulatory proceedings in which we may be involved from time to time;
- risks associated with the collection of sales or consumption taxes;
- our ability to implement, both internally and externally, information technology improvements and to respond to technological changes, interruptions and security breaches;
- natural disasters, pandemics, acts of war or terrorism and other external events affecting us, our customers or our suppliers; and
- our ability to hire and retain key employees.

These risks are not exhaustive. Other sections of this Form 10-K include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements made in this Form 10-K speak only as of the date of this report. We do not intend, and do not undertake any obligation, to update any forward-looking statements to reflect future events or circumstances after the date of such statements, except as required by law.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Market and Industry Data

This Form 10-K contains market, industry and government data and forecasts that have been obtained from publicly available information, various industry publications and other published industry sources. We have not independently verified the information and cannot make any representation as to the accuracy or completeness of such information. None of the reports and other materials of third-party sources referred to in this Form 10-K were prepared for use in, or in connection with, this report.

Trademarks and Tradenames

We have a number of registered trademarks, including Ambulatory Infusion Made Easy®, Biomed Made Easy®, BlockPain Dashboard®, EXPRESSTech® and Infusion Made Easy®. These and other trademarks of ours appearing in this report are our property. Solely for convenience, trademarks and trade names of ours referred to in this Form 10-K may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and trade names. This report may contain additional trade names and trademarks of other companies. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

PART I

Item 1. Business.

Background

The Company is a Delaware corporation, formed in 2005. It operates through operating subsidiaries, including InfuSystem Holdings USA, Inc., a Delaware corporation ("Holdings"), InfuSystem, Inc., a California corporation ("ISI"), First Biomedical, Inc., a Kansas corporation ("First Biomedical"), and IFC, LLC, a Delaware limited liability company ("IFC").

Business Concept and Strategy

We are a leading national health care service provider, facilitating outpatient care for Durable Medical Equipment manufacturers and health care providers. We provide our products and services to hospitals, oncology practices, ambulatory surgery centers, and other alternate site health care providers. Our headquarters is in Rochester Hills, Michigan, and we operate our business from a total of seven locations in the United States ("U.S.") and Canada.

Our services are provided under a two-platform model. Our lead platform, Integrated Therapy Services ("ITS"), provides the last-mile solution for clinic-to-home healthcare where the continuing treatment involves complex Durable Medical Equipment and services. Our second platform, Durable Medical Equipment Services ("DME Services"), supports our ITS platform and leverages the Company's strong service orientation to win incremental business from our direct payer clients.

We believe InfuSystem has a lot to offer the healthcare community. Over the last 30 plus years, we have developed a unique expertise and service offering that Durable Medical Equipment manufacturers and health care providers are using to reduce costs, improve service, and most importantly, provide welcome options for patients who want to continue their healthcare treatments from home. We perfected our ITS model in oncology and have proven that we can extend this model into other Durable Medical Equipment therapies. Key is the ability to leverage our existing platforms – the new therapies do not require building a new infrastructure; we simply add incrementally to the systems already in place (e.g., sales, clinical, logistics, revenue cycle management, and biomedical services).

ITS is presented as a "turnkey" solution allowing our health care provider customers to focus on the practice of medicine. InfuSystem provides the Durable Medical Equipment and treatment consumables, handles the logistics around orders and deliveries, provides 24x7 nursing support relating to the provided equipment, assumes responsibility for third-party payer Durable Medical Equipment billing, and handles biomedical services (inspection, repair, certification and replacement) for the Durable Medical Equipment. DME Services are provided as a "concierge" offering, whereby InfuSystem leverages its strong service orientation to provide incremental services to our health care provider customers on a direct payer model. DME Services include equipment rental and sales, consumable sales, and biomedical support services.

InfuSystem competes for and retains its business primarily on the basis of its long participation and strong reputation in the Durable Medical Equipment space, its long-standing relationships with Durable Medical Equipment manufacturers and its health care provider customers, and the high levels of service it provides. Current barriers to entry for potential competitors are created by our: (i) growing number of third-party payer networks under contract, which included nearly 800 third-party payer networks as of December 31, 2022, an increase of 4% over the prior year period; (ii) economies of scale, which allow for predictable reimbursement and less costly purchase and management of the pumps, respectively; (iii) established, long-standing relationships as a provider of pumps to outpatient oncology practices in the U.S. and Canada; (iv) our large pump fleet of ambulatory and large volume infusion pumps for rent and for sale, which may allow us to be more responsive to the needs of physicians, outpatient oncology practices, hospitals, outpatient surgery centers, homecare practices, patient rehabilitation centers and patients than a new market entrant; (v) seven geographic locations in the U.S. and Canada that allow for same-day or next-day delivery of pumps; (vi) our growing team of field-based and traveling biomedical technicians; and (vii) a wide array of pump repair and service capabilities. We do not perform any research and development on pumps, but we have made, and continue to make, investments in our information technology.

ITS Segment

The ITS segment's core purpose is to seek opportunities to grow our business by leveraging our unique know-how in clinic-to-home health care involving Durable Medical Equipment, our logistics and billing capabilities, our growing network of third-party payers under contract, and our clinical and biomedical capabilities. This leverage may take the form of new products and/or services, strategic alliances, joint ventures and/or acquisitions. The leading service within our ITS segment is to supply electronic ambulatory infusion pumps and associated disposable supply kits to private oncology clinics, infusion clinics and hospital outpatient oncology clinics to be utilized in the treatment of a variety of cancers, including colorectal cancer and other

disease states ("Oncology Business"). Colorectal cancer is the fourth most prevalent form of cancer in the U.S., according to the American Cancer Society, and the standard of care for the treatment of colorectal cancer relies upon continuous chemotherapy infusions delivered via ambulatory infusion pumps. One of the goals for the ITS segment is to expand into treatment of other types of cancers. In 2022, our Oncology Business approximated 91% of our total ITS segment net revenues. In 2022, we generated approximately 47% of our total ITS segment net revenues from treatments for colorectal cancer and 44% of our ITS segment net revenues from treatments for non-colorectal disease states. There are a number of approved treatment protocols for pancreatic, head and neck, esophageal and other types of cancers, as well as other disease states which present opportunities for growth. There are also a number of other drugs currently approved by the U.S. Food and Drug Administration (the "FDA"), as well as agents in the pharmaceutical development pipeline, which we believe could potentially be used with continuous infusion protocols for the treatment of diseases other than colorectal cancer. Additional drugs or protocols currently in clinical trials may also obtain regulatory approval over the next several years. If these new drugs or protocols obtain regulatory approval for use with continuous infusion protocols, we expect the pharmaceutical companies to focus their sales and marketing efforts on promoting the new drugs and protocols to physicians.

Furthermore, our Oncology Business focuses mainly on the continuous infusion of chemotherapy. Continuous infusion of chemotherapy can be described as the gradual administration of a drug via a small, lightweight, portable infusion pump over a prolonged period of time. A cancer patient can receive his or her medicine anywhere from one to 30 days per month depending on the chemotherapy regimen that is most appropriate to that individual's health status and disease state. This may be followed by periods of rest and then repeated cycles with treatment goals of progression-free disease survival. This drug administration method has replaced intravenous push or bolus administration in specific circumstances. The advantages of slow continuous low doses of certain drugs are well documented. Clinical studies support the use of continuous infusion chemotherapy for decreased toxicity without loss of anti-tumor efficacy. The 2015 National Comprehensive Cancer Network ("NCCN") Guidelines recommend the use of continuous infusion for treatment of numerous cancer diagnoses. We believe that the growth of continuous infusion therapy is driven by three factors: evidence of improved clinical outcomes; lower toxicity and side effects; and a favorable reimbursement environment.

The use of continuous infusion has been demonstrated to decrease or alter the toxicity of a number of cytotoxic, or cell killing, agents. Higher doses of drugs can be infused over longer periods of time, leading to improved tolerance and decreased toxicity. For example, the cardiotoxicity (heart muscle damage) of the chemotherapy drug Doxorubicin is decreased by schedules of administration according to The Chemotherapy Source Book by Michael C. Perry. Nausea, vomiting, diarrhea and decreased white blood cell and platelet counts are all affected by duration of delivery. Continuous infusion can lead to improved tolerance and patient comfort while enhancing the patient's ability to remain on the chemotherapy regimen. Additionally, the lower toxicity profile and resulting reduction in side effects enables patients undergoing continuous infusion therapy to continue a relatively normal lifestyle, which may include continuing to work, going shopping, and caring for family members. We believe that the partnering of physician management and patient autonomy provide for the highest quality of care with the greatest patient satisfaction.

We believe that oncology practitioners have a heightened sensitivity to providing quality service and to their ability to obtain reimbursement for services they provide. Simultaneously, CMS and private insurers are increasingly focused on evidence-based medicine to inform their reimbursement decisions — that is, aligning reimbursement with clinical outcomes and adherence to standards of care. Continuous infusion therapy is a main component of the standard of care for certain types of cancer because clinical evidence demonstrates superior outcomes. Payers' recognition of this benefit is reflected in their relative reimbursement policies for clinical services related to the delivery of this care.

Additional areas of focus for our ITS segment are as follows:

- Pain Management - providing our ambulatory pumps, products, and services for pain management in the area of post-surgical continuous peripheral nerve block.
- Wound Care - launched in November 2022, the Company established a partnership, SI Wound Care, LLC ("SI Wound Care"), with Sanara MedTech Inc. ("Sanara"). The partnership will focus on delivering a complete wound care solution targeted at improving patient outcomes, lowering the cost of care, and increasing patient and provider satisfaction. The partnership is expected to enable InfuSystem to offer innovative products including Cork Medical LLC's ("Cork") negative pressure wound therapy ("NPWT") devices and supplies and Sanara's advanced wound care product line to new customers through the jointly controlled entity.
- Acquisitions - we believe there are opportunities to acquire smaller, regional health care service providers, in whole or in part that perform similar services to us but do not have the national market access, network of third-party payer contracts or operating economies of scale that we currently enjoy. We may also pursue acquisition opportunities of companies that perform similar services, but offer different therapies or utilize different devices.

- Lymphedema Therapy – Lymphedema therapy includes providing patient care and customer service, pneumatic compression devices and associated garments through our partnership with Bio Compression Systems, Inc. to outpatients, initially targeting our existing acute care and oncology customers, estimated to be 20% of the multi-billion-dollar Lymphedema market.
- Information technology-based services - we also plan to continue to capitalize on key new information technology-based services such as EXPRESS, InfuBus or InfuConnect, Pump Portal, DeviceHub and BlockPain Dashboard®.

The payer environment within our ITS segment is in a constant state of change. We continue to extend our considerable breadth of payer networks under contract as patients move into different insurance coverage plans, including Medicaid and Insurance Marketplace products. In some cases, this may slightly reduce our aggregate billed revenues payment rate but result in an overall increase in collected revenues, due to a reduction in concessions. Consequently, we are increasingly focused on revenues net of concessions.

DME Services Segment

Our DME Services segment's core service is to: (i) sell or rent new and pre-owned pole-mounted and ambulatory infusion pumps and other Durable Medical Equipment; (ii) sell treatment-related consumables; and (iii) provide biomedical recertification, maintenance and repair services for oncology practices as well as other healthcare site settings, including hospitals, home care and home infusion providers, skilled nursing and acute care facilities, pain centers and others. We purchase new and pre-owned pole-mounted and ambulatory infusion pumps from a variety of sources on a non-exclusive basis. We repair, refurbish and provide biomedical certification for the devices as needed. The pumps are then available for sale, rental or to be used within our ambulatory infusion pump management service. Our acquisition of FilAMed, a privately-held biomedical services company, on January 31, 2021 has supplemented the Company's existing biomedical recertification, maintenance and repair services for acute care facilities and other alternate site settings including home care and home infusion providers, skilled nursing facilities, pain centers and others. Our acquisition of OB Healthcare Corporation ("OB Healthcare"), a privately-held biomedical services company, on April 18, 2021 further develops and expands InfuSystem's DME Services segment by adding field service capabilities and complements the Company's purchase of FilAMed.

Services

ITS Segment

Our core service within our ITS segment is our Oncology Business. After delivering our ambulatory pumps to oncology offices, infusion clinics, and hospital and outpatient chemotherapy clinics, we then directly bill and collect payment from payers and patients for the use of these pumps. At any given time, our pumps are in the possession of these facilities, on a patient, in transit, or in our facilities for cleaning, calibration and storage as reserves for increased demand.

After a physician determines that a patient is eligible for ambulatory infusion pump therapy, the physician arranges for the patient to receive an infusion pump and provides the necessary chemotherapy drugs. The physician and nursing staff train the patient in the use of the pump and initiate service. The physician bills the payers, which may include Medicare, Medicaid, third-party payer companies or patients for the physician's professional services associated with initiating and supervising the infusion pump administration, as well as the supply of drugs. We directly bill (i) payers, (ii) facilities of our Medicare patients, and (iii) patients for the use of the pump and related disposable supplies. Billing to payers requires coordination with patients and physicians who initiate the service, as physicians' offices must provide us with appropriate documentation (patient's insurance information, physician's order, an acknowledgement of benefits that shows receipt of equipment by the patient, and, in some cases, physician's progress notes) in order for us to submit a bill to the payers. We provide assistance to uninsured patients that cannot afford our pumps via our financial hardship program – a program that usually matches what our physician practices provide as long as the uninsured patients meet certain criteria. This billing process is handled from our Rochester Hills, Michigan location.

In addition to providing high quality and convenient care, we believe that our business offers significant economic benefits for patients, providers and payers.

- Our clinical support team employs oncology, pain, Intravenous Certified, and Oncology Certified registered nurses trained on ambulatory infusion pump equipment who staff our 24x7 customer service hotline to address questions that patients may have about their pump treatment, the infusion pumps or other medical or technical questions related to the pumps.

- Physicians use our services to outsource the capital commitment, pump service, maintenance and billing and administrative burdens associated with pump ownership. Our services also allow the doctor to continue a direct relationship with the patient and to receive professional service fees for setting up the treatment and administering the drugs.

- We provide methods for the physician offices to deliver the appropriate paperwork for billing through a number of electronic means including EXPRESS and InfuConnect reducing the required effort on the employees of the physician offices.

- We believe our services are attractive to payers because such services are generally less expensive than hospitalization or standalone home health care.

Also, within ITS, we offer pain management services via electronic ambulatory infusion pumps for post-operative pain management using our pumps along with a numbing agent and a continuous nerve block catheter – continuous peripheral nerve block ("CPNB"). Using CPNB for the management of post-operative pain, which usually lasts two to three days after surgery, can result in reduced pain for the patient, increased satisfaction scores for the surgical center or hospital, and reduced need for post-operative opioid pain medication. These services include our patient care call center interaction offering support to patients and the review and collection of pain score patient outcome data for outpatient surgery centers using our proprietary BlockPain Dashboard®.

DME Services Segment

Other services we offer are classified under our DME Services segment and include the rental, sale or leasing and servicing of pole-mounted and ambulatory infusion pumps to oncology practices, hospitals and other clinical settings. These pumps are available for daily, weekly, monthly or annual rental periods. We also sell treatment consumables that can be used in conjunction with the pumps we sell and rent.

In addition to sales, rental and leasing services, we also provide biomedical maintenance, repair and certification services for the devices we offer as well as for devices owned by customers but not acquired from us. We operate pump service and repair "Centers of Excellence" from all of our locations across the U.S. and Canada and employ a staff of highly-trained technicians to provide these services. Our main Center of Excellence for service is our Lenexa, Kansas facility. In addition to the maintenance and repair services we perform at these facilities, we offer similar services that can be performed directly at our customer locations nation-wide through our team of field-based and traveling biomedical technicians.

As of December 31, 2022, our rental fleet of pole-mounted pumps, ambulatory pumps and NPWT medical equipment for both our ITS and DME Services segments had a historical cost of $99.2 million, up from $91.9 million at the end of 2021, and included approximately 125 makes and models of equipment dedicated to our rental services. Additionally, as of December 31, 2022 and 2021, we had a fleet of new and used pole-mounted pumps, ambulatory pumps and NPWT medical equipment with a historical cost of $2.8 million and $1.8 million, respectively, for sale or rental.

Information Technology

Our Information Technology ("IT") department is focused on not only supporting our internal IT infrastructure needs, but also supporting our revenue cycle management infrastructure including our electronic medical record technology ("EMR") that allows medical facilities to use our infusion pumps and services via our solutions such as EXPRESS and InfuConnect. This focus has enabled current billing information to be transferred to us from participating facilities electronically and automatically. Our focus on IT solutions resulted in the development of EXPRESS, a product powered by our InfuBus data integration platform, and provides for paperless delivery of the appropriate information for InfuSystem to bill payers that:

- eliminates all paper;
- provides an enhanced visibility as a result of real time status and reporting;
- reduces risk of error;
- automates treatment logs, pump assignments, tracking and physician's orders;
- provides a secure scanner for easy pump assignment to patients; and
- removes interruptions from physician practices' daily schedules, and standardizes data flow for clinics and hospitals with multiple locations.

Relationships with Physician Offices

As of December 31, 2022, we had business relationships with clinical oncologists in over 2,150 outpatient oncology clinics. Although this represents a substantial number of the oncologists in the U.S., we believe that we can continue to expand

our network to further penetrate the oncology market. Based on our retention rates and the positive results of our professional customer satisfaction research, we believe our relationships with physician offices are strong.

We believe that, in general, we do not compete directly with hospitals and physician offices to treat patients. Rather, by providing products and services to hospitals and physician offices and other care facilities and providers, we believe that we assist other providers in meeting increasing patient demand and managing institutional constraints on capital and manpower due to the nature of limited resources in hospitals and physician offices.

Physician practices in the oncology field are following the overall healthcare practices trend to consolidate. However, as of December 31, 2022, we had gained more facilities than we had lost. We expect this trend to continue for the foreseeable future.

Employees

As of December 31, 2022, we had 438 employees, including 420 full-time employees and 18 part-time or contract employees. None of our employees are unionized.

Material Suppliers

We supply a wide variety of pumps and associated equipment, as well as disposables and ancillary supplies. The majority of our pumps are electronic infusion pumps. Smiths Medical, Inc. and Moog Medical Devices Group each supplied more than 10% of the ambulatory pumps purchased by us in 2022. The Company has a supply agreement in place with each of these suppliers. Certain "spot" purchases are made on the open market subject to individual negotiation. We also supply NPWT medical equipment, as well as related disposables and ancillary supplies.

Seasonality

Revenues may be seasonal due to the impact of co-pays and deductibles for patients' insurance that traditionally reset each January. This has been further impacted by changes in the insurance industry as it responds to increased government regulation. Also, rental customers tend to make buy versus rent decisions late in the year as customer capital budgets are being finalized, impacting sales revenue in the second half of the year, predominantly in the fourth quarter. Furthermore, as the Company's liquidity has improved, opportunistic pump purchases are made from time to time. These opportunistic pump purchases also allow for opportunistic pump sales, which could be material. The timing of such purchases and sales vary within the course of a year.

Environmental Laws

We are required to comply with applicable federal, state and local environmental laws regulating the disposal of cleaning agents used in the process of cleaning medical equipment, as well as the disposal of sharps and blood products used in connection with the pumps and medical equipment. We do not believe that compliance with such laws has a material effect on our business.

Significant Customers

We have sought to establish contracts with as many third-party payer organizations as commercially practicable, in an effort to ensure that reimbursement is not a significant obstacle for providers who recommend continuous infusion therapy and wish to utilize our services. A third-party payer organization is a health care payer or a group of medical services payers that contracts to provide a wide variety of health care services to enrolled members through participating providers such as us. A payer is any entity that pays on behalf of a member patient.

As of December 31, 2022, we had contracts with nearly 800 third-party payer networks, an increase of 4% over the prior year period. Material terms of contracts with third-party payer organizations are typically a pre-negotiated fee schedule rate or a then-current proprietary fee schedule rate for equipment and supplies provided. The majority of these contracts generally provide for a term of one year, with automatic one-year renewals, unless we or the contracted payer elect not to renew. We also contract with various other third-party payer organizations, Medicaid, commercial Medicare replacement plans, self-insured plans, facilities of our Medicare patients and numerous other insurance carriers. No single payer or customer represented more than 10% of net revenue in 2022, 2021 or 2020.

Competitors

We believe that our competition primarily consists of national, regional, and hospital-owned Durable Medical Equipment providers and service companies, physician providers and home care infusion providers and the competitive products and services they offer. An estimate of the number of competitors is not known or reasonably available, due to the wide variety in type and size of the market participants described below. We are not aware of any industry reports with respect to the competitive market described below. The description of market segments and business activities within those market segments is based on our experiences in the industry.

- National Durable Medical Equipment Providers and Service Companies: Other national providers and service companies have offerings similar to us. These products and service offerings include, but are not limited to, third-party reimbursement, direct rental and sale of infusion electronic and disposal pumps and related products and services for patients in the home, oncology clinics, ambulatory surgery centers, hospitals and other sites of care.

- Regional Durable Medical Equipment Providers: Regional Durable Medical Equipment providers act as distributors for a variety of medical products. We believe regional Durable Medical Equipment provider sales forces generally consist of a relatively small number of salespeople, usually covering several states. Regional Durable Medical Equipment providers tend to carry a limited selection of infusion pumps and their salespeople generally have limited resources. Regional Durable Medical Equipment providers usually do not have 24x7 nursing services. We believe that Regional Durable Medical Equipment providers have relatively few third-party payer contracts, which may prevent these providers from being paid at acceptable levels and may also result in higher out-of-pocket costs for patients.

- Hospital-Owned Durable Medical Equipment Providers: Many hospitals have in-house Durable Medical Equipment providers to supply basic equipment. In general, however, these providers have limited capital and tend to stock a small inventory of infusion pumps. We believe that hospital-owned providers have limited ability to grow because of limited patient populations. Growth from outside of the hospital may pose a challenge because hospitals typically will not provide referrals to competitors, instead preferring to offer patients a choice of non-hospital-affiliated Durable Medical Equipment providers.

- Physician Providers: A limited number of physicians maintain an inventory of their own infusion pumps and provide them to patients for a fee. However, we believe that pump utilization in this area tends to be low and the costs associated with ongoing supplies, preventative maintenance and repairs can be relatively high. Moreover, we believe that a high percentage of Durable Medical Equipment claims by doctors are rejected by payers upon first submission, requiring a physician's staff to spend significant time and effort to resubmit claims and receive payment for treatment. The numerous service and technical questions from patients may present another significant cost to a physician provider's staff.

- Home Care Infusion Providers: Home care infusion providers provide chemotherapy drugs and services to allow for in-home patient treatment. We believe that home care infusion treatment can be very costly and that many patients do not carry insurance coverage that pay for home-based infusion services, resulting in larger out-of-pocket costs. Because home care treatments may take as long as six months, these costs can be high and can result in higher patient co-payments. We believe that home care providers may also be reluctant to offer 24x7 coverage or additional patient visits, due to capped fees.

Regulation of Our Business

Our business is subject to various regulations. Specifically, as a registered Medicare supplier of Durable Medical Equipment and related supplies, we must comply with supplier standards established by CMS regulating Medicare suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS Supplier Standards"). The DMEPOS Supplier Standards consist of 30 requirements that must be met in order for a DMEPOS supplier to be eligible to receive payment for a Medicare-covered item. Some of the more significant DMEPOS Supplier Standards require us to (i) advise Medicare beneficiaries of their option to purchase certain equipment, (ii) honor all warranties under state law and not charge Medicare beneficiaries for the repair or replacement of equipment or for services covered under warranty, (iii) permit CMS agents to conduct on-site inspections to ascertain compliance with the DMEPOS Supplier Standards, (iv) maintain liability insurance in prescribed amounts, (v) refrain from contacting Medicare beneficiaries by telephone, except in certain limited circumstances, (vi) answer questions and respond to complaints of beneficiaries regarding the supplied equipment, (vii) disclose the DMEPOS Supplier Standards to each Medicare beneficiary to whom we supply equipment, (viii) maintain a complaint resolution procedure and record certain information regarding each complaint, (ix) maintain accreditation from a CMS approved accreditation organization, and (x) meet certain specified surety bond requirements.

We are also subject to the provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which are designed to protect the security and confidentiality of certain protected health information. Under HIPAA, we must provide patients access to certain records and must notify patients of our use of protected health information and patient privacy rights. Moreover, HIPAA sets limits on how we may use individually identifiable health information and prohibits the use of patient information for marketing purposes. The adoption of the American Recovery and Reinvestment Act of 2009 ("ARRA") includes a new breach notification requirement that applies to breaches of unsecured health information occurring on or after September 23, 2009. We are subject to regulations in the various states in which we operate. We believe we are in material compliance with all such regulations.

Available Information

Our Internet address is www.infusystem.com. On this website, we post the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC"): our Annual Reports on Form 10-K; our Quarterly Reports on Form 10-Q; our Current Reports on Form 8-K; our proxy statements related to our annual stockholders' meetings; and any amendments to those reports or statements. All such filings are available on our website free of charge. The charters of our audit, nominating and governance and compensation committees and our Code of Business Conduct and Ethics Policy are also available on our website and in print to any stockholder who requests them. The content on our website is not incorporated by reference into this Form 10-K unless expressly noted.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the material risks described below, together with the other information contained in this Form 10-K. If any of the following events occur, our business, financial condition, results of operations and cash flows may be materially adversely affected.

RISK FACTORS RELATING TO OUR BUSINESS AND THE INDUSTRY IN WHICH WE OPERATE

Our business is substantially dependent on third-party reimbursement. Any change in the overall health care reimbursement system may adversely impact our business.

Our revenues are substantially dependent on third-party reimbursement. We are paid directly by private insurers and, in some cases, governmental agencies, often on a fixed fee basis, for the use of continuous infusion equipment and related disposable supplies provided to patients. If the average fees allowable by private insurers or governmental agencies were reduced, the negative impact on revenues could have a material effect on our business, financial condition, results of operations and cash flows. Also, if amounts owed to us by patients and insurers are reduced or not paid on a timely basis, we may be required to increase our concessions and/or decrease our revenues.

Changes in the health care reimbursement system often create financial incentives and disincentives that encourage or discourage the use of a particular type of product, therapy or clinical procedure. Such changes may be impacted by the growth in ACOs, reduction of providers by payers, the use of lower cost rental networks and other factors. Market acceptance of continuous infusion therapy may be adversely affected by changes or trends within the health care reimbursement system. Changes to the health care reimbursement system that favor other technologies or treatment regimens that reduce reimbursements to providers or treatment facilities, including increasing competitive pressures from home health care and other companies that use our services, may adversely affect our ability to market our services profitably. Overall, such dependency and potential changes could materially and adversely affect our business, financial condition, results of operations and cash flows.

Our business is substantially dependent on estimates of collectible revenue from third-party reimbursement.

Our revenues are substantially dependent on estimates of collectible revenue from third-party reimbursement. Due to the complex nature of third-party reimbursement for the use of continuous infusion equipment and related disposable supplies provided to patients, we must estimate, based upon historical averages, the amount of collectible revenue that may be derived from each patient treatment. If average reimbursement rates diverge from historical levels, the estimates of such revenue may diverge from actual collections.

We utilize statistical methods to account for such changes, but there can be no assurance that the revenue reported in any period will ultimately be collected. Any recognized revenue related to third-party reimbursement from prior periods, which remains uncollected until written off from accounts receivable, will negatively impact revenues in the period in which it is written off. Thus, over time, recognized revenue net of concessions will approximate total collections.

The loss of a relationship with one or more third-party payers could negatively impact our business.

Our contracts for reimbursement with third-party payers are often for a term of one year, with automatic one-year renewals, unless we or the contracted payer elect not to renew. These evergreen contracts are subject to termination upon written notice. One or more terminations could have a material and adverse effect on our business, financial condition, results of operations and cash flows.

Any federal government shutdown may adversely impact our business.

Our revenues are dependent on private insurers and governmental agencies. In the absence of any bipartisan agreement in the federal government with respect to payments from governmental agencies, our revenues could be reduced. In addition, any federal government shutdown could also have a material and adverse impact on our business, financial condition, results of operations and cash flows.

Payer concentration may adversely impact our business.

As of December 31, 2022, we had contracts with nearly 800 third-party payer networks, an increase of 4% over the prior year period. Material terms of contracts with third-party payer organizations are typically a pre-negotiated fee schedule rate or a then-current proprietary fee schedule rate for equipment and supplies provided. The majority of these contracts generally provide for a term of one year, with automatic one-year renewals, unless we or the contracted payer elect not to renew. We also contract with various other third-party payer organizations, Medicaid, commercial Medicare replacement plans, self-insured plans, facilities of our Medicare patients and numerous other insurance carriers. No single payer represented more than 10% of net revenue in 2022, 2021 or 2020. To the extent such dependency was to occur, significant fluctuations in revenues, results of operations and liquidity could arise if any significant contracted payer reduces its reimbursement for the services we provide.

Our billing process is dependent on meeting payer claims processing guidelines which are subject to change at the discretion of the payers. Such changes would materially impact our ability to bill and the timing of such billings, which could materially and adversely impact our net revenues and cash flows, which impact would be even greater if such changes are made by one of our larger payers.

The continued consolidation of physician practices, outpatient infusion clinics, oncology clinics, homecare providers and hospitals, increases the concentration of decision makers whom either choose to use our ambulatory electronic pumps within our Oncology Business or directly rent, lease or purchase pumps or supplies from us.

While we make every effort to benefit from such concentration, it could materially and adversely affect our business, financial condition, results of operations and cash flows.

Increased focus on early detection and diagnostics may adversely affect our business.

An increased focus on lowering health care spending via improved diagnostic testing (i.e., defensive medicine) and patient monitoring could materially and negatively affect our business. A large portion of our ambulatory infusion pumps are dedicated to a specific form of cancer (i.e., colorectal). As a result of rising health care costs, there may be a demand for more cost-effective approaches to disease management, specifically for colorectal cancer, as well as for emphasis on screening and accurate diagnostic testing to facilitate early detection of potentially costly, severe afflictions. Any change in the approach to treatment of colorectal cancer could have a material and adverse impact on our business, financial condition, results of operations and cash flows.

If future clinical studies demonstrate that oral medications or other therapies that do not use our electronic ambulatory pumps are at least as effective as continuous infusion therapy, our business could be adversely affected.

Ongoing clinical trials are currently evaluating and comparing the therapeutic benefits of current continuous infusion-based regimens with various oral medication regimens. If these clinical trials demonstrate that oral medications provide equal or greater therapeutic benefits and/or demonstrate reduced side effects compared to prior oral medication regimens, our revenues and overall business could be materially and adversely affected. Additionally, if new oral medications or other therapies that do not utilize our ambulatory electronic pumps are introduced to the market that are superior to existing oral therapies, physicians' willingness to prescribe continuous infusion-based regimens could decline, which would materially and adversely affect our business, financial condition, results of operations and cash flows.

Our success is impacted by the availability of the chemotherapy drugs that are used in our continuous infusion pump systems.

We primarily derive our revenues from the rental of ambulatory infusion pumps to oncology patients through physicians' offices and chemotherapy clinics. A shortage in the availability of chemotherapy drugs that are used in the continuous infusion pump system, which has occurred in the past, could have a material and adverse effect on our business, financial condition, results of operations and cash flows.

We are dependent on our Medicare Supplier Number.

We are required to have a Medicare Supplier Number in order to have the ability to bill Medicare for services provided to Medicare patients. Furthermore, all third-party and Medicaid contracts require us to have a Medicare Supplier Number. We are required to comply with Medicare DMEPOS Supplier Standards in order to maintain such number. If we are unable to comply with the relevant standards, we could lose our Medicare Supplier Number. Without such number, we would be unable to continue our various third-party and Medicaid contracts. A significant portion of our revenues are dependent upon our Medicare Supplier Number, the loss of which would materially and adversely affect our business, financial condition, results of operations and cash flows.

The CMS requires that all Durable Medical Equipment providers must be accredited by a CMS-approved accreditation organization. On February 17, 2009, we initially received accreditation from CHAP, and we have remained accredited to date. If we lost our accredited status, our business, financial condition, revenues and results of operations would be materially and adversely affected.

The impact of U.S. health care reform legislation on us remains uncertain.

The ACA has perpetuated the development of alternative provider payment models by CMS and the major national commercial payers. These payment models do not replace the current fee-for-service models nor replace current payer contracts, but rather provide additional financial incentives to certain "accountable" providers to improve quality and lower cost. The implications for the Company will come from the provider networks that are forming in order to integrate and coordinate care under these alternative models with CMS and the commercial payers. These provider networks include ACOs, patient-centered primary care medical homes, specialty medical homes, networks accepting bundled payment programs, and other "performance" networks that contract with CMS and commercial payers under alternative payment models that financially reward improved quality and lower medical cost. The relationship between us and our provider practices and facilities that are participating in these provider networks under alternative payment models will depend on (i) the extent to which these provider networks give priority to the medical cost associated with our Durable Medical Equipment services and (ii) whether our services are seen as part of a care delivery model that delivers higher value – higher quality at a lower cost.

Our failure to perform under these alternative payment models, or under similar models or conditions introduced by future legislation, could have a material adverse impact on our business, financial condition, results of operations and cash flows.

We rely on independent suppliers for our products. Any delay or disruption in the supply of products, particularly our supply of electronic ambulatory pumps, may negatively impact our operations.

Our infusion pumps and related consumables are obtained from outside vendors. The majority of our new pumps are electronic infusion pumps which are supplied to us by two major suppliers: Smiths Medical, Inc. and Moog Medical Devices Group. The loss or disruption of our relationships with outside vendors, including pumps, parts, or supply recall or pump end-of-life announcements or availability of related proprietary consumable supplies, could subject us to substantial delays in the delivery of pumps or services provided to customers. From time to time, we or our suppliers may experience supply chain disruptions due to circumstances beyond our or our suppliers' control, such as the 2020 outbreak of COVID-19. Significant delays in the delivery or service of pumps or related proprietary consumable supplies could result in possible cancellation of orders and the loss of customers. Our inability to provide pumps to meet delivery schedules could have a material adverse effect on our reputation in the industry, as well as on our business, financial condition, results of operations and cash flows.

We face periodic reviews and billing audits from governmental and private payers and these audits could have adverse results that may negatively impact our business.

As a result of our participation in the Medicaid program and our registration in the Medicare program, we are subject to various governmental reviews and audits to verify our compliance with these programs and applicable laws and regulations. We also are subject to audits under various government programs in which third-party firms engaged by CMS conduct extensive

reviews of claims data and medical and other records to identify potential improper payments under the Medicare program. Private pay sources also reserve the right to conduct audits. If billing errors are identified in the sample of reviewed claims, the billing error can be extrapolated to all claims filed which could result in a larger overpayment than originally identified in the sample of reviewed claims. Our costs to respond to and defend reviews and audits may be significant and could have a material adverse effect on our business, financial condition, results of operations and cash flows. Moreover, an adverse review or audit could result in:

- required refunding or retroactive adjustment of amounts we have been paid by governmental or private payers;
- state or Federal agencies imposing fines, penalties and other sanctions on us;
- loss of our right to participate in the Medicare program, state programs, or one or more private payer networks; or
- damage to our business and reputation in various markets.

Any one of these results could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our failure to maintain controls and processes over billing and collecting could have a significant negative impact on our Consolidated Financial Statements.

The collection of accounts receivable is a significant challenge and requires constant focus and involvement by management and ongoing enhancements to information systems, billing center operating procedures and proper staffing levels. If we are unable to properly bill and collect our accounts receivable, our results could be materially and adversely affected. While management believes that our staffing, controls and processes are satisfactory, there can be no assurance that accounts receivable collectability will remain at current levels.

State licensure laws for Durable Medical Equipment suppliers are subject to change. If we fail to comply with any state laws, we will be unable to operate as a Durable Medical Equipment supplier in such state and our business operations will be adversely affected.

As a Durable Medical Equipment supplier operating in all 50 states, we are subject to each state's licensure laws regulating Durable Medical Equipment suppliers. State licensure laws for Durable Medical Equipment suppliers are subject to change and we must ensure that we are continually in compliance with the laws of all 50 states. In the event that we fail to comply with any state's laws governing the licensing of Durable Medical Equipment suppliers, we will be unable to operate as a Durable Medical Equipment supplier in such state until we regain compliance. We may also be subject to certain fines and/or penalties and our business operations could be materially and adversely affected.

Our customer concessions may not be adequate to cover actual losses.

Our third-party payer contracts do not guarantee annual inflationary increases, typical of the Durable Medical Equipment payer contracting environment. Contracted reimbursement rates are either subject to increases or decreases in CMS program rates or, if not indexed to government rates, are frozen until those payer contracts are reopened and renegotiated. While we monitor reimbursement levels to identify specific payer reimbursement rates that have eroded and renegotiate such rates, we may not be able to maintain or improve overall reimbursement levels, thereby compromising the adequacy of the predicted customer concessions.

We may also face reduced reimbursements from private third-party payers. In addition, our customers may be unable to make timely payments to us. Although we maintain allowances for estimated losses resulting from the inability of our customers to make required payments, we cannot guarantee that we will continue to experience the same loss rates that we have in the past. If we begin to experience an increase in our loss rates in excess of our allowances, it could materially and adversely impact our business, financial condition, results of operations and cash flows.

Our growth strategy includes expanding into treatment for cancers other than colorectal cancer. There can be no assurance that continuous infusion-based regimens for these other cancers will become standards of care for large numbers of patients or that we will be successful in penetrating these different markets.

An aspect of our growth strategy is to expand into the treatment of other cancers, such as head, neck and gastric cancers. This population of patients will expand only if clinical trial results for new drugs and new combinations of drugs demonstrate superior outcomes for regimens that include continuous infusion therapy relative to alternatives. No assurances can be given that these new drugs and drug combinations will be approved or will prove superior to oral medication or other treatment

alternatives. In addition, no assurances can be given that we will be able to penetrate successfully any new markets that may develop in the future or manage the growth in additional resources that would be required.

The industry in which we operate is intensely competitive and ever-changing. If we are unable to successfully compete with our competitors, our business operations may suffer.

The drug infusion industry is highly competitive. Some of our competitors and potential competitors, including some of the practices that we service, have significantly greater resources than we do for information technology, marketing and sales. As a result, they may be better able to compete for market share, even in areas in which our services may be superior. The industry is subject to technological changes and such changes may put our current fleet of pumps, smart pump licensing, our information technology solutions or our other technological-based solutions at a competitive disadvantage. Furthermore, the healthcare industry, in general, is experiencing market consolidation, reducing the number of decision makers. If we are unable to effectively compete in our market, our business, financial condition, results of operations and cash flows may be materially and adversely affected.

Our industry is dependent on regulatory guidelines that affect our billing practices. If our competitors do not comply with these regulatory guidelines, our business could be adversely affected.

Aggressive competitors may not fully comply with rules regarding CMS and other payers' billing and documentation requirements. Competitors, who do not meet the same standards of compliance that we do with respect to billing regulations, may put us at a potential competitive disadvantage. We are a participating provider with Medicare and as of December 31, 2022, we were under contract with nearly 800 third-party payer networks, all of which have very stringent guidelines. If our competitors do not comply with these regulatory guidelines, we could be put at a potential competitive disadvantage and our business, financial condition, results of operations and cash flows could be material and adversely affected.

Although we do not manufacture the products we distribute, if one of the products distributed by us proves to be defective or is misused by a health care practitioner or patient, we may be subject to liability that could adversely affect our financial condition and results of operations.

Although we do not manufacture the pumps that we distribute, a defect in the design or manufacture of a pump distributed or serviced by us, or a failure of pumps distributed by us to perform for the use specified, could have a material and adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Misuse of the pumps distributed by us by a practitioner or patient that results in injury could similarly subject us to liability. Any substantial underinsured loss could have a material and adverse effect on our business, financial condition, results of operations and cash flows. Furthermore, any impairment of our reputation could have a material and adverse effect on our revenues and prospects for future business.

We intend to continue to pursue opportunities for the further expansion of our business through strategic alliances and/or joint ventures. Future strategic alliances and/or joint ventures may require significant resources and/or result in significant unanticipated costs or liabilities to us.

We intend to continue to pursue opportunities for the further expansion of our business through strategic alliances and/or joint ventures. Any future strategic alliances or joint ventures will depend on our ability to identify suitable partners, negotiate acceptable terms for such transactions and obtain financing, if necessary. These investments require significant managerial attention, which may be diverted from our other operations.

If we engage in strategic acquisitions, we may experience significant costs and difficulty in assimilating operations or personnel, which could threaten our future growth.

If we make any acquisitions, we could have difficulty assimilating operations, technologies and products and services. In addition, we could have difficulty integrating or retaining personnel and maintaining employee morale as we take steps to combine the personnel and business cultures of separate organizations into one and to eliminate duplicate positions and functions. It may also be difficult for us to preserve important relationships with others, such as strategic partners, customers, and suppliers, who may delay or defer decisions on agreements with us, or seek to change existing agreements with us, because of the acquisition. In addition, acquisitions may involve entering markets in which we have no or limited direct prior experience. The occurrence of any one or more of these factors could disrupt our ongoing business, distract our management's and employees' attention from our ongoing business operations, result in decreased operating performance and increase our expenses. Moreover, our profitability may suffer because of acquisition-related costs or amortization of intangible assets. Furthermore, we may have to incur debt or issue equity securities in future acquisitions. The issuance of equity securities would dilute our existing stockholders.

We may be unable to maintain adequate working relationships with health care professionals.

We seek to maintain close working relationships with respected physicians and medical personnel in hospitals and universities. We rely on these professionals to assist us in the development of proprietary service and improvements to complement and expand our existing service and product lines. If we are unable to maintain these relationships, our ability to market and sell new and improved products and services could decrease and future operating results could be unfavorably affected.

If we fail to comply with applicable governmental or accrediting bodies' regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal, state health care, and accreditation bodies' laws and regulations, including those pertaining to fraud and abuse and patients' rights, are applicable to our business. The laws that are applicable to our business include:

- the federal health care program Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving or providing remuneration, directly or indirectly, to induce (i) the referral of an individual, for an item or service or (ii) the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us that promote medical devices, provide medical device management services and may provide coding and billing advice to customers;
- HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ in significant ways from state to state and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially and adversely affect our business, financial condition, results of operations and cash flows. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Failure to protect our intellectual property could substantially harm our business and operating results.

In order to protect our trade secrets and other confidential information, we rely in part on confidentiality agreements with our employees, consultants and third parties with whom we have relationships. These agreements may not effectively prevent disclosure of trade secrets and other confidential information and may not provide an adequate remedy in the event of misappropriation of trade secrets or any unauthorized disclosure of trade secrets and other confidential information. In addition, others may independently discover our trade secrets and confidential information and, in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce or determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. Failure to obtain or maintain trade secret protection, or our competitors' acquisition of our trade secrets, could materially and adversely affect our competitive business position.

Covenants in our current and any future debt agreements restrict our business.

Our 2021 Credit Agreement contains and the agreements that govern our future indebtedness may contain, covenants that restrict our ability to and the ability of our subsidiaries to, among other things:

- engage in a transaction that results in a change of control, as defined by the 2021 Credit Agreement;
- create, incur, assume or suffer to exist any lien upon any of our property, assets or revenues;
- make certain investments or acquisitions;

- create, incur, assume or suffer to exist certain indebtedness;
- merge, dissolve, liquidate, consolidate or sell all or substantially all of our assets;
- make any disposition or enter into any agreement to make any disposition;
- repurchase outstanding stock from the open market; and
- declare or make, directly or indirectly, any dividend or other restricted payment, or incur any obligation (contingent or otherwise) to do so.

These covenants may restrict our ability to operate our business. Our failure to comply with these covenants could result in an event of default that, if not cured or waived, could result in reduced liquidity for the Company and could have a material and adverse effect on our ability to operate our business, financial condition, results of operations and cash flows. Additionally, our ability to pay interest and repay the principal for our indebtedness is dependent upon our ability to manage our business operations, generate sufficient cash flows to service such debt and the other factors discussed in this section. Our 2021 Credit Agreement also contains certain financial covenants. As of December 31, 2022, we were in compliance with all the covenants contained in the 2021 Credit Agreement, however, there can be no assurance that we will be able to manage any of the risks associated with debt agreements successfully.

Economic uncertainty or economic deterioration could adversely affect us.

There continues to be global economic uncertainty, as well as increased inflation, heightened interest rates and a recessionary environment. Ongoing political changes and conflicts in the U.S. and abroad continue to contribute to global economic uncertainty and volatility in the global financial markets. In February 2022, Russian forces launched significant military actions against Ukraine, which has caused significant international conflict, including sanctions, tensions and military actions. In addition, the effects of the COVID-19 pandemic have contributed to economic uncertainty. Continued economic uncertainty may continue to drive stock market and interest rate volatility, increased inflation and adversely impact consumer confidence, product demand, and our ability to refinance our debt. Economic conditions, along with our operating performance, may also materially and adversely impact our ability to access the financial markets. Accordingly, our future business and financial results are subject to uncertainty. If economic conditions deteriorate in the future, our future revenues and financial results could be materially and adversely affected.

Changes in tax laws or challenges to our tax positions could adversely affect our business, results of operations and financial condition.

We are subject to income taxes as well as non-income based taxes in federal and various state jurisdictions. Changes in tax laws, including, for example, those resulting from the U.S. federal tax legislation commonly referred to as the Coronavirus Aid, Relief, and Economic Security (CARES) Act, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates in future periods and otherwise adversely affect our tax positions and/or our tax liabilities. The full impact of the CARES Act on us may change significantly as regulations, interpretations and rulings relating to the CARES Act are issued and additional changes in U.S. federal and state tax laws are made in the future. There can be no assurance that our effective tax rates, tax payments, tax credits or incentives will not be adversely affected by these or other initiatives.

We are subject to audits by tax authorities from time to time in federal and state jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes and penalties. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes of these audits could have a material impact on our results of operations.

The value of our net operating loss carryforwards may become impaired if we do not generate sufficient future taxable income required to utilize all or a portion of our net operating loss carryforwards prior to their expiration.

The Company's U.S. federal net operating loss carryforward for tax purposes was $35.7 million at December 31, 2022, resulting in a federal deferred tax asset of $7.5 million. Approximately $29.1 million of the Company's U.S. federal net operating loss carryforwards will begin to expire in various years beginning in 2031. The Company's realization of its deferred tax assets including the loss carryforwards is dependent upon many factors, including, but not limited to, the Company's ability to generate sufficient taxable income in sufficient amounts. There can be no assurance that we will generate the required amounts of taxable income before the expiration dates are reached.

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) Immediate parent owner is not changing - see attached letter * If making a change, provide current license number: WH 02347	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Catalent Pharma Solutions, LLC

Physical Address: 3031 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: (215) 501-1210 Website: www.catalent.com

Name of Designated Representative (DR): Christoper Blanton

Licensing Company Email: GMB-CPSLLC-PHL@catalent.com DR Email: GMB-CPSLLC-PHL@catalent.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Adira Medica, LLC
Address: 585 Turner Industrial Way City: Aston State: PA Zip: 19104

Name: McKesson Corp
Address: 1 John Henry Drive City: Robbinsville State: NJ Zip: 08691

Name: ICS Direct AmericourceBergen Drug Corp.
Address: L5025 Plano Parkway City: Carrollton State: TX Zip: 75010

Name: RXSource Corp
Address: 74-556 Edward Avenue City: Richmond Hill State: ON Zip: L4C9Y5

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

Section S: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Catalent Pharma Solutions, Inc. (immediate parent company of applicant)
Corporation/Organization Name: Catalent Pharma Solutions, LLC
Mailing Address: 3031 Red Lion Road
City: Philadelphia State: PA Zip: 19114
Telephone: (215) 501-1210 Email: GMB-CPSLLC-PHL@catalent.com
Contact Person Name: Brandon Getsinger

Section 6: Partnership

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Section 7: Sole Owner

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*: See Attachment 1

Date of Event/Arrest	Disposition Date	State	City	County
April 25, 2017	April 25, 2017	SC	Columbia	Lexington
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
PY17234	South Carolina Board of Pharmacy			
Reason/Charge				
Attachment				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
N/A	N/A			
Name of Business/Industry/Entity				
Catalent Pharma Solutions, LLC				

Provide explanation below:

On April 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $5,000 fine to the South Carolina Board of Pharmacy in settlement of a matter involving the shipment of clinical trial product into South Carolina without a license.

Original Signature (electronic, copies or stamps not accepted)

Nov. 04, 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*: See Attachment 1

Date of Event/Arrest	Disposition Date	State	City	County
July 25, 2017	July 25, 2017	AL	Birmingham	Shelby

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
17-L-0071	Alabama Board of Pharmacy

Reason/Charge
Attachment

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

Name of Business/Industry/Entity
Catalent Pharma Solutions, LLC

Provide explanation below:

On July 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $1,500 fine to the Alabama Board of Pharmacy in settlement of a matter involving the discipline from the South Carolina BOP regarding the shipment of clinical trial product into South Carolina without a license. According to the Alabama Board, a violation of any other state's licensing regulations (in this case, South Carolina's regulations) constitutes a violation of Alabama's regulations.

Original Signature (electronic, copies or stamps not accepted)

Nov. 04, 2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*: **Attachment 1**

Date of Event/Arrest	Disposition Date	State	City	County
July 8, 2024	Pending	AL	Birmingham	Shelby

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-L-0259	Alabama Board of Pharmacy

Reason/Charge
Attachment

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

Name of Business/Industry/Entity
Catalent Pharma Solutions, LLC

Provide explanation below:

On July 8, 2024, the Catalent Pharma Solutions, LLC facility located at 3031 Red Lion Road in Philadelphia, PA ("Catalent Philadelphia Site") received a Notice of Hearing from the Alabama Board of Pharmacy. The Notice requires Catalent to appear before the Alabama Board on September 17, 2024 (or otherwise come to a resolution with the Board prior to that date) to provide evidence and testimony in response to the Board's allegation that the Catalent Philadelphia Site did not timely notify the Alabama Board about a change in the Designated Representative for the Catalent Philadelphia Site. The Board's rules require notification to be made within ten (10) days of a change in the Designated Representative. The Catalent Philadelphia Site, through its legal counsel, filed a Motion to Continue the hearing in order to obtain additional discovery from the Alabama Board. The Alabama Board did not object to the Motion; thus, on August 8, 2024, The Alabama Board granted Catalent's Motion to Continue and rescheduled the hearing for October 29, 2024. A "Joint Motion to Continue" has been granted and reset for March 18, 2025.

Original Signature (electronic, copies or stamps not accepted)

Nov. 04, 2024
Date

Catalent

14 Schoolhouse Road
Somerset, NJ 08873
catalent.com

+ 1 888 SOLUTION (76588466)

Explanations of Disciplinary Actions

Catalent Pharma Solutions, LLC, 3031 Red Lion Road, Philadelphia, PA 19114

1. South Carolina Board of Pharmacy – PHILADELPHIA

On April 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $5,000 fine to the South Carolina Board of Pharmacy in settlement of a matter involving the shipment of clinical trial product into South Carolina without a license.

2. Alabama Board of Pharmacy - PHILADELPHIA

On July 25, 2017, the Catalent Pharma Solutions, LLC site located in Philadelphia, PA (Red Lion Road) paid a $1,500 fine to the Alabama Board of Pharmacy in settlement of a matter involving the discipline from the South Carolina BOP regarding the shipment of clinical trial product into South Carolina without a license. According to the Alabama Board, a violation of any other state's licensing regulations (in this case, South Carolina's regulations) constitutes a violation of Alabama's regulations.

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE STATE BOARD OF PHARMACY

In the Matter of: **Catalent Pharma Solutions, LLC,** **Applicant.**	**ORDER**

This matter first came before the Nonresident Permit Subcommittee ("Committee"), appointed by the State Board of Pharmacy ("Board"), on April 25, 2017, for a hearing on the application of the above-named applicant ("Applicant") for a nonresident wholesaler/distributor/manufacturer permit. The Applicant appeared before the Committee through its designated representative, Terry Jackson, as well as its Associate General Counsel for Regulatory Matters, Robert Ciolek, Esquire. Applicant was represented by Jon Wallace, Esquire. At its June 14, 2017, meeting with a quorum present, the Board considered the Committee's recommendation and the transcript of the Committee's hearing. The Board adopted the Committee's recommendation that the application be approved, and the permit shall issued subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars for shipping into South Carolina without a permit. Since the hearing, Applicant has tendered the fine to the Board.

Applications of this type are governed by S.C. Code §§ 40-43-83, 40-43-86, 40-43-89 (2011, as amended), and/or Reg. 99-43, as amended.

FINDINGS OF FACT

1. Applicant applied for a permit for its facility located in Philadelphia, PA.

2. Applicant manufactures clinical supply materials.

3. Applicant's representative admitted that Applicant has previously shipped prescription drugs to South Carolina without first obtaining a permit from this Board.

4. Applicant otherwise meets the requirements for the Permit for which it applied.

CONCLUSIONS OF LAW

In an application hearing, "(t)he applicant shall demonstrate to the satisfaction of the board that the applicant meets all requirements for the issuance of a license." S.C. Code Ann. § 40-1-130 (2011, as amended). Thus, the burden of proof in an application for licensure or certification is on the Applicant to provide full, complete, and accurate responses to all questions on the application

and to demonstrate that it is qualified for the license sought.

S.C. Code Ann. §40-43-83(I)(2011) requires a permit for the sale or distribution of legend (prescription) drugs in this state, and expressly includes manufacturers within or without the state. S.C. Code Ann. § 40-43-89 (2011) requires a facility located outside of this State that distributes prescription drugs or devices in this State to have a permit issued by the Board prior to distribution. S.C. Code Ann. § 40-43-140(A)(3) states that facilities requiring permits may not operate unless a permit has been issued by the board. Pursuant to S.C. Code Ann. § 40-43-140(A)(1)(2011), the Board may suspend, revoke, deny, or refuse to renew the permit or impose disciplinary action authorized for violations of the Pharmacy Act. Pursuant to S.C. Code Ann. §§ 40-43-140(A)(2), a person who distributes or delivers drugs or devices in this State without a required permit is subject to a fine imposed by the Board not to exceed one thousand dollars for each offense, in addition to such other disciplinary action the Board may take.

Applicant has met the qualifications for the permit, but violated the Pharmacy Practice Act by regularly distributing prescription drugs or devices into this State without a permit. Therefore, the Board concludes that it is appropriate to issue the permit subject to the prior payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars.

NOW, THEREFORE, IT IS ORDERED THAT:

The Application is approved, and the permit shall be issued subject to the payment of a civil penalty in the amount of Five Thousand and 00/100 ($5,000.00) Dollars, receipt of which is hereby acknowledged by the Board.

AND IT IS SO ORDERED.

STATE BOARD OF PHARMACY

Carole Small Russell

CAROLE SMALL RUSSELL, R.Ph.
Board Chair

June 16, 2017

South Carolina Department of Labor, Licensing & Regulation

STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

CATALENT PHARMA SOLUTIONS, LLC
PY . 17234

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, June 16, 2017, served the Order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s) to the following address:

CATALENT PHARMA SOLUTIONS, LLC
3031 RED LION RD
PHILADELPHIA PA 19114

JONATHAN A. WALLACE, ESQUIRE
715 KING STREET
CHARLESTON, SC 29403

Karen Y Newton

Karen Y. Newton
Administrative Coordinator
SC Department of Labor, Licensing
and Regulation

IN THE MATTER OF:	)	**BEFORE THE ALABAMA**
	)	
CATALENT PHARMACY SOLUTIONS	)	**STATE BOARD OF PHARMACY**
	)	
Manufacturer/Wholesaler/ Distributor Applicant	)	**CASE NO: 17-L-0071**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Catalent Pharma Solutions, LLC (hereinafter referred to as "Catalent") relating to disciplinary action in the State of South Carolina.

Pursuant to Code of Alabama (1975) § 41-22-12(f) the parties, through counsel, have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Catalent has violated the provisions of the applicable Board Rule based upon the conduct set out above; however, the Board grants the application of Catalent for a Manufacturer/Wholesaler/Distributor permit for the location at 3031 Red Lion Road, Philadelphia, PA 19114 expressly contingent upon the payment of a fine in the amount of One Thousand Five Hundred and NO/100 Dollars ($1,500.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Catalent attempt to discharge the same.

2. That Catalent expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to a statement or notice of charges, the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Catalent further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Catalent hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and complaint.

5. That Catalent agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Catalent acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Catalent acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 1 day of August, 2017.

CATALENT PHARMA SOLUTIONS, LLC

By: _____
Its: VP & Deputy GC

_____
Michael Whisonant, Attorney for Catalent Pharma Solutions, LLC

DONE this the _____ day of 8/8/2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch
Buddy Bunch, R.Ph.
President

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

Alabama Hearing:

On July 8, 2024, the Catalent Pharma Solutions, LLC facility located at 3031 Red Lion Road in Philadelphia, PA ("Catalent Philadelphia Site") received a Notice of Hearing from the Alabama Board of Pharmacy. The Notice requires Catalent to appear before the Alabama Board on September 17, 2024 (or otherwise come to a resolution with the Board prior to that date) to provide evidence and testimony in response to the Board's allegation that the Catalent Philadelphia Site did not timely notify the Alabama Board about a change in the Designated Representative for the Catalent Philadelphia Site. The Board's rules require notification to be made within ten (10) days of a change in the Designated Representative. The Catalent Philadelphia Site, through its legal counsel, filed a Motion to Continue the hearing in order to obtain additional discovery from the Alabama Board. The Alabama Board did not object to the Motion; thus, on August 8, 2024, The Alabama Board granted Catalent's Motion to Continue and rescheduled the hearing for October 29, 2024. A "Joint Motion to Continue" has been granted and reset for March 18, 2025.

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
CATALENT PHARMA SOLUTIONS LLC	)	**CASE NO.: 22-L-0259**
Manufacturer Permit No.: 195336	)	

ORDER GRANTING "JOINT MOTION TO CONTINUE"

This matter is before the undersigned by way of a "Joint Motion to Continue" from Respondent Catalent Pharma Solutions, LLC (hereinafter referred to as "Respondent") and the Alabama State Board of Pharmacy (hereinafter referred to as the "Board"), by and through counsel for both parties, on August 6, 2024. This matter is scheduled for final hearing before the Board on October 29, 2024 at 8:00 A.M. The Motion states additional time is needed for settlement discussions in order to resolve this matter. The Board has no objection to the Motion. After having considered the Motion, the undersigned is of the opinion that for good cause the "Joint Motion to Continue" is due to be and hereby **GRANTED**.

This matter is reset for March 18, 2025 at 8:00 A.M. and from time to time thereafter as may be required by the Board for the purpose of the hearing to determine the charges served on the Respondent.

All previously issued subpoenas, if any, remain in full force and effect and are lawful Orders for witnesses to appear on the above date and time.

All other aspects of the "Notice of Hearing" and Statement of Charges remain unchanged. The time limits imposed in the Scheduling Order shall remain the same in relation to the new hearing date. However, the specific deadline for informing Board's counsel of settlement proposals as entered

in Paragraph (4) of the Scheduling Order is modified to reflect the Board's meeting date of February 18, 2025.

DONE and ORDERED this the 23rd day of September, 2024.

/s/ James F. Hampton
JAMES F. HAMPTON
Administrative Hearing Officer
Alabama State Board of Pharmacy
4267 Lomac Street
Montgomery, Alabama 36106
(334) 213-0213
jhall@jamesfhampton.com

cc: Catalent Pharma Solutions LLC
c/o Mr. Michael W. Whisonant, Jr., Esq. (mwhisonant@rjalfelaw.com)
Mr. Brett H. Knight, Esq. (bknight@rjalfelaw.com)
Ms. Donna C. Yeatman, RPh, Executive Secretary
Ms. Jennifer Muro Neumann, Esq.

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	BOARD OF PHARMACY
CATALENT PHARMA SOLUTIONS LLC	)	
	)	CASE NO.: 22-L-0259
Manufacturer	)	
Permit No.: 195336	)	

NOTICE OF HEARING

TO: Catalent Pharma Solutions LLC
3031 Red Lion Road
Philadelphia, Pennsylvania 19114

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34, § 34-23-52, § 34-23-92(12), § 34-23-132 and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on Sept 17, 2024 at 8:00 a.m., at the State Board of Pharmacy Hearing Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine whether your permit should be revoked, suspended or otherwise disciplined in that it is alleged that you have failed to comply with all applicable state laws and regulations. Disciplinary action may include administrative fines not to exceed $1,000 per violation; and/or revocation, suspension, or denial of your license(s); and/or such other discipline as may be ordered by the Board. Code of Alabama (1975), § 34-23-33. You have the right to be represented by counsel at your own expense, to respond and present evidence and argument on all material issues, to cross-examine all witnesses who testify against you, and to request that witnesses and/or documents be subpoenaed on your behalf. Please refer to the enclosed Standard Scheduling Order for further information regarding responding to the charges, witnesses, exhibits, and prehearing matters.

STATEMENT OF CHARGES

COMES NOW Complainant Donna C. Yeatman, as Executive Secretary of the Alabama State Board of Pharmacy and, on behalf of the Alabama State Board of Pharmacy ("the Board"), charges Respondent **Catalent Pharma Solutions LLC** as follows:

Nicholas Leonarduzzi became your new designated representative on July 8, 2022, but you did not notify the Board until August 18, 2022.

Further, on August 8, 2017, you agreed to a Consent Order with the Alabama State Board of Pharmacy wherein you admitted to receiving discipline from the South Carolina Board of

Pharmacy involving shipping into that State without a valid permit. You agreed to pay a fine of $1,500 to the Alabama State Board of Pharmacy. See Exhibit A attached hereto.

VIOLATIONS

If proven true, you will be in violation of the following:

Code of Alabama (1975), § 34-23-33(a)(12), R. 680-X-2.23(9)(a)(3) in that a change in a permit holder's Designated Representative requires notification to the Board within (10) days.

PRAYER FOR RELIEF

WHEREFORE, Complainant, in her capacity as the Executive Secretary of the Alabama State Board of Pharmacy, requests that, upon hearing and proof, Respondent be found guilty of the aforementioned violations and that the Alabama State Board of Pharmacy take such disciplinary actions as it deems necessary.

Dated this the 8th day of July, 2024.

ALABAMA STATE BOARD OF PHARMACY

Donna C Yeatman

By: Donna C. Yeatman Executive Secretary

EXHIBIT A

IN THE MATTER OF:	BEFORE THE ALABAMA
CATALENT PHARMACY SOLUTIONS	STATE BOARD OF PHARMACY
Manufacturer/Wholesaler/ Distributor Applicant	CASE NO: 17-L-0071

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Catalent Pharma Solutions, LLC (hereinafter referred to as "Catalent") relating to disciplinary action in the State of South Carolina.

Pursuant to Code of Alabama (1975) § 41-22-12(f) the parties, through counsel, have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Catalent has violated the provisions of the applicable Board Rule based upon the conduct set out above; however, the Board grants the application of Catalent for a Manufacturer/Wholesaler/Distributor permit for the location at 3031 Red Lion Road, Philadelphia, PA 19114 expressly contingent upon the payment of a fine in the amount of One Thousand Five Hundred and NO/100 Dollars ($1,500.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Catalent attempt to discharge the same.

2. That Catalent expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to a statement or notice of charges, the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Catalent further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Catalent hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and complaint.

5. That Catalent agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Catalent acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Catalent acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 1 day of August, 2017.

CATALENT PHARMA SOLUTIONS, LLC

By: _____
Its: VP & DEPUTY G.C.

_____
Michael Whisonant, Attorney for Catalent Pharma Solutions, LLC

DONE this the _____ day of 8/8/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Buddy Bunch
Buddy Bunch, R.Ph.
President

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

ALABAMA STATE BOARD OF PHARMACY

SCHEDULING ORDER

In order to administer the matter, set for hearing in a manner fair to the Respondent and the Alabama State Board of Pharmacy and consistent with the interest in completing this matter in the shortest possible time, this Order is issued. Read carefully; failure to comply with the below listed requirements may result in sanctions.

IT IS ORDERED that the Respondent and the Board are directed to comply with each of the following directives:

(1) DISCOVERY

All Requests for Production and other discovery requests must be submitted to be received by the Administrative Hearing Officer and a copy to the Board's counsel or Respondent's counsel if request by the Board, no later than forty (40) days before the scheduled hearing at:

James F. Hampton
Administrative Hearing Officer
Alabama Board of Pharmacy
4267 Lomac Street
Montgomery, Alabama 36106
E-mail: jfh@jamesfhampton.com

With a copy to the Respondent and Board's Counsel

Jennifer Muro Neumann, Esquire
Post Office Box 381082
Birmingham, AL 35238
E-mail: jennifermuroneumann@gmail.com

(2) REQUESTS FOR CONTINUANCE

All requests for continuances of the matter shall be submitted to be received by the Administrative Hearing Officer no later than thirty (30) days before the scheduled hearing with a copy to the Board's counsel or Respondent and if not, unless there are emergency circumstances, the hearing WILL NOT be continued.

(3) PLEADINGS

All other pleadings shall be submitted to be received by the Administrative Hearing Officer no later than fifteen (15) days before the scheduled hearing with a copy to the Board's counsel or Respondent if submitted by the Board. Pleadings shall be submitted with the style, case number and containing a certificate of service.

(4) CONSENT ORDER/SETTLEMENT PROPOSALS

If you are interested in a settled proposal from the Board, you must inform Board's counsel seven days in advance of the Board meeting in the month prior to the scheduled hearing. For the attached Statement of Charges and Notice of Hearing the prior Board meeting is 8/20/24. Unless emergency circumstances exist, proposals submitted after the above date will not be considered.

(5) COPIES

Prior to the hearing the parties shall prepare a sufficient number of copies of documents which are proposed to be introduced into evidence at the administrative hearing. With the exception of the Statement of Charges and Notice of Hearing, documents which are proposed to be introduced into evidence at the administrative hearing shall not be presented to the Administrative Hearing Officer prior to the hearing unless otherwise ordered.

(7) REPRESENTATION

Individuals may represent themselves before the Board. Legal entities such as corporations, LLCs and partnerships must be represented by an attorney licensed to practice in the State of Alabama. Attorneys representing Respondents in administrative hearings before the Board shall file a Notice of Appearance with the Administrative Hearing Officer with a copy to the Board's counsel. Attorney should compare their calendar to the scheduled hearing date before accepting representation to avoid conflict. In the event, an attorney who is not a member of the Alabama Bar, is representing a Respondent in a matter to be heard in an administrative hearing, the attorney shall make Application for Admission Pro Hac Vice To Practice Under Rule VII of The Rules Governing Admission To The Alabama State Bar.

DONE and ORDERED this the 9 day of July, 2024.

JAMES F. HAMPTON
ADMINISTRATIVE HEARING OFFICER

Copies to:
Respondent
Mrs. Jennifer Muro Neumann, Esq.
Mrs. Wendy Passmore, Alabama Board of Pharmacy

Donna C. Yeatman, R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
www.albop.com

ALABAMA
BOARD OF PHARMACY

MEMBERS 2024

Christy Garmon, PharmD
President

Gary Mount, PharmD
Vice President

Thomas H. Cobb, PharmD
Treasurer

Stacy Sharp Giles, R.Ph.

John J. Brooklere, R.Ph.

Date
July 9, 2024

To: CATALENT PHARMA SOLUTIONS LLC
3031 RED LION ROAD
PHILADELPHIA, PA/19114

FROM: WENDY PASSMORE, OPERATONS MANAGER
EMAIL- WPASSMORE@ALBOP.COM
FAX - 205-803-6481

RE: ADMINISTRATIVE HEARINGS

CASE #: 22-L-0259

Your hearing is scheduled for **September 17, 2024** at 8:00 AM

Please provide the following information if different than above.

NAME: _____

ADDRESS: _____

_____

Please note: The administrative hearing will proceed as scheduled with or without your attendance.

☐ I plan to attend the Hearing.

☐ I do not plan to attend the Hearing.

☐ I will be represented by the Attorney listed below:

ATTORNEY'S NAME: _____ PHONE # _____

ADDRESS: _____

EMAIL _____

****

WHILE A CONTINUANCE IS NOT AUTOMATIC, ANY REQUEST FOR ONE MUST BE FILED AND RECEIVED BY THE BOARD'S HEARING OFFICER THIRTY (30) DAYS PRIOR TO YOUR SCHEDULED HEARING DATE.

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification See Attachment 2 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration See Attachment 3 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment 4	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment 4		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment 5	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment 6	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** N/A	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment 7	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Pharma Solutions, LLC

Facility Name

Joseph Ferraro

Print Name of Authorized Person Submitting Application

Joseph Ferraro

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

Nov. 04, 2024

Date

Board Use Only	Date Received: 11/5/24	Amount: $1000-cc ✓

NABP ACCREDITED
DRUG DISTRIBUTOR

Catalent Pharma Solutions, LLC

located at

3031 Red Lion Road, Philadelphia, PA 19114

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

11/23/2023 to 11/22/2026
Period of Accreditation

An official website of the United States government Here's how you know

FDA

Search FDA.gov

Current through February 4, 2025

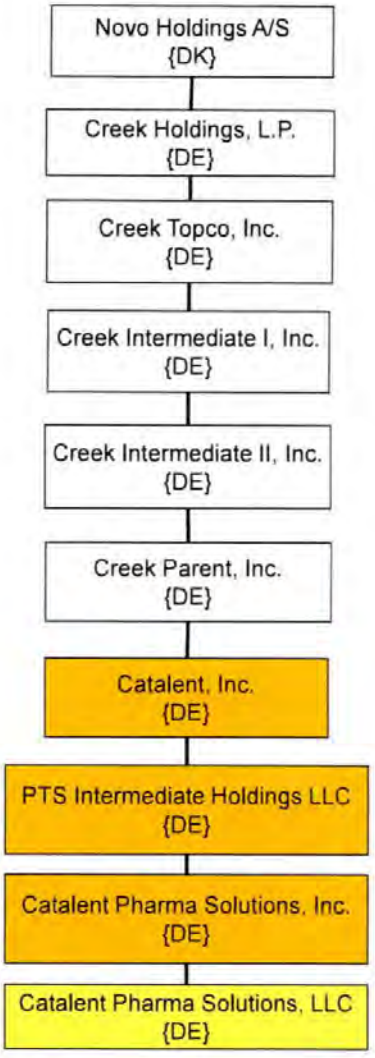
You have searched Unfinished drug products

Search Results: *'11014'*

Back to Search Page

Showing 1 to 50 of 270 entries Show 50 entries

NDC Package Code	Strength	Dosage Form	Labeler Name	Non Proprietary Name	Substance Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	DEA	Listing Record Certified Through
11014-0012-1	.5ug/1	CAPSULE, GELATIN COATED	Catalent Pharma Solutions, LLC	Calcitriol	CALCITRIOL	08/10/2009	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0012-1) / 12500 CAPSULE, GELATIN COATED in 1 BAG 10-AUG-09	N/A	12/31/2025
11014-0014-1	75mg/1	CAPSULE, LIQUID FILLED	Catalent Pharma Solutions, LLC	bexarotene	BEXAROTENE	12/29/1999	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0014-1) / 3000 CAPSULE, LIQUID FILLED in 1 BAG 29-DEC-99	N/A	12/31/2025
11014-0021-1	.25ug/1	CAPSULE	Catalent Pharma Solutions, LLC	Calcitriol	CALCITRIOL	03/27/2006	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0021-1) / 30000 CAPSULE in 1 BAG 27-MAR-06	N/A	12/31/2025
11014-0033-1	25mg/1	CAPSULE, LIQUID FILLED	Catalent Pharma Solutions, LLC	cyclosporine	CYCLOSPORINE	07/14/1995	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0033-1) / 14000 CAPSULE, LIQUID FILLED in 1 BAG 14-JUL-95	N/A	12/31/2025
11014-0034-1	100mg/1	CAPSULE, LIQUID FILLED	Catalent Pharma Solutions, LLC	cyclosporine	CYCLOSPORINE	07/14/1995	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0034-1) / 3600 CAPSULE, LIQUID FILLED in 1 BAG 14-JUL-95	N/A	12/31/2025
11014-0040-1	100mg/1	CAPSULE, LIQUID FILLED	Catalent Pharma Solutions, LLC	cyclosporine	CYCLOSPORINE	03/02/1990	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0040-1) / 4000 CAPSULE, LIQUID FILLED in 1 BAG 02-MAR-90	N/A	12/31/2025
11014-0041-1	25mg/1	CAPSULE, LIQUID FILLED	Catalent Pharma Solutions, LLC	cyclosporine	CYCLOSPORINE	03/02/1990	N/A	DRUG FOR FURTHER PROCESSING	1 BAG in 1 BOX (11014-0041-1) / 16000 CAPSULE, LIQUID FILLED in 1 BAG 02-MAR-90	N/A	12/31/2025



Catalent

Entity Name	EIN
Novo Holdings A/S	98-0571483
Creek Holdings, L.P.	99-1344651
Creek Topco, Inc.	99-1107684
Creek Intermediate I, Inc.	99-1344400
Creek Intermediate II, Inc.	99-1356828
Creek Parent, Inc.	99-1280758
Catalent, Inc.	20-8737688
PTS Intermediate Holdings LLC	27-3738365
Catalent Pharma Solutions, Inc.	13-3523163
Catalent Pharma Solutions, LLC	13-4268760

Novo Holdings A/S
Ultimate Parent

Creek Holdings, L.P.
100% owned by Novo Holdings A/S, Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

Creek TopCo, Inc.
100% owned by Creek Holdings, L.P., Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

Creek Intermediate I, Inc.
100% owned by Creek TopCo, Inc., Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

Creek Intermediate II, Inc.
100% owned by Creek Intermediate I, Inc., Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

Creek Parent, Inc.
100% owned by Creek Intermediate II, Inc., Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

Catalent, Inc.
100% owned by Creek Parent, Inc., Tuborg Havnevej 19, DK 2900 Hellerup, Denmark

PTS Intermediate Holdings LLC
100% owned by Catalent, Inc., 14 Schoolhouse Road, Somerset, NJ 08873

Catalent Pharma Solutions, Inc.
100% owned by PTS Intermediate Holdings LLC, 14 Schoolhouse Road, Somerset, NJ 08873

Catalent Pharma Solutions, LLC
100% owned by Catalent Pharma Solution, Inc., 14 Schoolhouse Road, Somerset, NJ 08873

Attachment 5

Corporate Officer Information

14 Schoolhouse Road
Somerset, NJ 08873
(732) 537-6200

Alessandro Maselli
President & Chief Executive Officer
<1% Ownership

Ramon J. Ceron
Vice President & Treasurer
<1% Ownership

Joseph Ferraro
Senior Vice President, General Counsel & Secretary
<1% Ownership

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT PHARMA SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT PHARMA SOLUTIONS, LLC" WAS FORMED ON THE FIFTH DAY OF NOVEMBER, A.D. 2003.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3724407 8300

SR# 20243733107

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

Authentication: 204434121

Date: 09-19-24

Attachment 9

Certificate of Registration

Certificate No. 1000003455
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

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

Category:

Manufacturer (Prescription)
Manufacturer (Non-Prescription)
Distributor (Prescription)
Distributor (Non-Prescription)
Devices

CATALENT PHARMA SOLUTIONS, LLC
3031 RED LION RD
PHILADELPHIA, PA 19114

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

Issuance Date: May 04, 2012
Expiration Date: The Last Day of May, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

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

Attachment 7

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0413411	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	07-02-2024

CATALENT PHARMA SOLUTIONS, LLC
3031 RED LION ROAD
PHILADELPHIA, PA 19114

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0413411	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5	DISTRIBUTOR	07-02-2024

CATALENT PHARMA SOLUTIONS, LLC
3031 RED LION ROAD
PHILADELPHIA, PA 19114

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SUR0073951

Application/License No. WH 02347

Catalent Pharma Solutions, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3031 Red Lion Road, Philadelphia, PA 19114 (Address of Applicant/Principal), as PRINCIPAL, and Argonaut Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is PO Box 469011, San Antonio, TX, 78246 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/31/2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of October, 2022.

APPLICANT/PRINCIPAL
Catalent Pharma Solutions, LLP

Authorized Representative

Steven Fasman, EVP, Chief Administrative Officer and Secretary

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Argonaut Insurance Company

Surety Company's Representative

Anne Potter, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Halina Kazmierczak

Witness Sandra Diaz

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Argonaut Insurance Company
Deliveries Only: 225 W. Washington, 24th Floor
Chicago, IL 60606
United States Postal Service: P.O. Box 469011, San Antonio, TX 78246
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the Argonaut Insurance Company, a Corporation duly organized and existing under the laws of the State of Illinois and having its principal office in the County of Cook, Illinois does hereby nominate, constitute and appoint

Sandra Diaz, Debra A Deming, Anne Potter, Beverly A Woolford, Valorie Spates, Jennifer L Jakaitis, Susan A Welsh, Peter Healy, Nancy Schnee, Aklima Noorhassan, Frances Rodriguez, Francesca Kazmierczak, Kemal Brkanovic

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of:

$97,550,000.00

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolution adopted by the Board of Directors of Argonaut Insurance Company:

"RESOLVED, That the President, Senior Vice President, Vice President, Assistant Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the Company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the Argonaut Insurance Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Argonaut Insurance Company has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer on the 19th day of November, 2021

Argonaut Insurance Company

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

by: _____

Gary E. Grose, President

STATE OF TEXAS
COUNTY OF HARRIS SS:

On this 19th day of November, 2021 A.D., before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY, to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate Seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written.

KATHLEEN M MEEKS
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP 07/15/25
NOTARY ID 557902-8

_____
(Notary Public)

I, the undersigned Officer of the Argonaut Insurance Company, Illinois Corporation, do hereby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 31st day of October 2022

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

_____
Austin W. King, Secretary

IF YOU HAVE QUESTIONS ON AUTHENTICITY OF THIS DOCUMENT CALL (833) 820 - 9137.

ARGO POWER OF ATTORNEY

FINANCIAL STATEMENT
ARGONAUT INSURANCE COMPANY
STATUTORY BASIS as of 12/31/2021

ASSETS

CASH & INVESTED ASSETS	$248,880,956
BONDS	$1,181,510,880
STOCKS	$674,977,267
INVESTMENT INCOME DUE AND ACCRUED	$5,760,648
PREMIUM BALANCES	$114,878,986
NET DEFERRED TAX ASSET	[illegible]
REINSURANCE RECOVERABLE	[illegible]
OTHER ASSETS	$40,514,092
TOTAL ASSETS	$2,392,360,630

LIABILITIES AND SURPLUS

UNEARNED PREMIUMS	$304,943,789
LOSSES	$595,583,927
LOSS ADJUSTMENT EXPENSES	$138,245,975
COMMISSIONS	$4,787,791
TAXES, LICENSES, AND FEES	$10,269,846
OTHER EXPENSES	$9,373,605
TOTAL [illegible]	[illegible]
CURRENT FEDERAL AND FOREIGN INCOME TAXES	$0
REMITTANCES AND ITEMS NOT ALLOCATED	$2,510,048
AMOUNTS WITHHELD/RETAINED BY COMPANY FOR OTHERS	$11,771,696
PAYABLES TO PARENT, SUBSIDIARIES, & AFFILIATES	$52,193,204
PAYABLE FOR SECURITIES	$3,599,489
PROVISION FOR REINSURANCE	$16,445,734
CEDED REINSURANCE PREMIUMS PAYABLE	$47,083,249
OTHER ACCRUED EXPENSES AND LIABILITIES	$1,597,617
TOTAL LIABILITIES	$1,321,201,703
COMMON CAPITAL STOCK	$4,500,000
GROSS PAID IN AND CONTRIBUTED SURPLUS	$525,520,936
UNASSIGNED SURPLUS	$541,137,991
TOTAL SURPLUS TO POLICYHOLDERS	$1,071,158,927
TOTAL LIABILITIES & SURPLUS	$2,392,360,630

Jace Westbrook, being duly sworn, says that he is Head of US Segment Accounting of Argonaut Insurance Company and that to the best of his knowledge, and belief, the foregoing statement is a true and correct statement of the financial condition of said Company as of the 31st of December, 2021.

Subscribed and sworn to before me this 5th day of April 2022

Notary Public

Julian Candler Westbrook III, Head of US Segment Accounting

CORPORATE SEAL ILLINOIS

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

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Catalent Pharma Solutions, LLC
Pharmacy/Wholesaler License # (if applicable): WH02347
Physical Address: 3031 Red Lion Road
City: Philadelphia State: PA Zip: 19114
Mailing Address (if different from physical address): Same as Above
City: State: Zip:
Telephone: (215) 501-1210 Website: www.catalent.com
Licensing Company Email: GMB-CPSLLC-PHL@catalent.com

Section 2: Personal Information

First: Christopher Middle: Allen Last: Blanton
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: 3031 Red Lion Road
City: Philadelphia State: PA Zip: 19114
Telephone: (215) 501-1210 Email: GMB-CPSLLC-PHL@catalent.com
Are you a citizen of the United States? ■ Yes ☐ No

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

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

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

School Name		From - To (MM/YY – MM/YY)	
North Carolina State University		08/06-12/09	
Address	City	State	Zip
Hillsborogh Street	Raleigh	NC	27695
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
The Citadel, the Military College of South Carolina		08/97-05/01	
Address	City	State	Zip
171 Moutrie Street	Charleston	SC	29409
Diploma/Degree obtained, if any			
B.S. Electrical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Gettys D. Broome High School		08/93-06/97	
Address	City	State	Zip
381 Cherry Hill Road	Spartanburg	SC	29307
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23 - present	[redacted]	Vorhees	NJ	[redacted]
From - To (MM/YY – MM/YY		City	State	
03/18 - 10/23		Philadelphia	PA	
From - To (MM/YY – MM/YY		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Catalent Pharma Solutions, LLC			08/24 - present	
Business Address		City	State	Zip
10381 Decatur Road		Philadelphia	PA	19154
Phone	Title		Number of Employed Hours	
(215) 501-1210	General Manager			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
HSC Independent Consulting			06/23 - 08/24	
Business Address		City	State	Zip
4 Hann Avenue		Vorhees	NJ	08043
Phone	Title		Number of Employed Hours	
(704) 775-0724	Independent Consultant			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
PCI Pharma Services			03/18 - 06/23	
Business Address		City	State	Zip
3001 Red Lion Road		Philadelphia	PA	19114
Phone	Title		Number of Employed Hours	
(215) 613-3600	VP, General Manager			
Description of Duties				

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Christopher Blanton, **certify that as the designated representative for**

Catalent Pharma Solutions, LLC,

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

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

Christopher Blanton
Print Name (First, Last)

Christopher A. Blanton
Original Signature (electronic, copies or stamps not accepted)

02/04/2025
Date

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

Christopher Blanton

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/04/2025

Date

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

State of Pennsylvania, ss. County of Philadelphia

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

Original Signature

02/04/2025

Date

Subscribed and Sworn to before me this 4th day of February 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
SAMANTHA RAE RINK - Notary Public
Philadelphia County
My Commission Expires October 17, 2026
Commission Number 1429182

(Seal)

Bruce, Patrice
Bundy, Andre Lamont
Buonfiglio, Dennis
Burgos, Zenobia
Burroughs, Eric Alvin
Burton, Troy
Bush, Elizabeth A
Bustos, Marive B
Butler, Katherine
By, Charlenna
Callands, Cameron
Cardone, Megan
Carrillo, Jose-Miguel
Cataldi, Brianna
Cedeno, Maria
Celis, John
Chacko, Joel
Charalabidis, Efthimia
Chu, Yim
Civil, Wolf
Clapps, Erica
Clapps, Jaclyn
Cobani, Arjana
Cobani, Brian
Cohen, Neil
Cooper, John D.
Corcoran, Zachary
Cross, Kelly
Cruz, Denzel
Cruz, Linette
Cruz, Ramon
Cruz, Yeiniely
Cucinotta, Michael A
Cuni, Arjana
Dailey, John R
Davis, Darnell
Davis, Hannah
Davis, Wanda D.
Dean, Derek
Defino, Nicholas Joseph
Delbrey, Daphnie
Delcastillo, Palmida
Delhomme, Josma
DHALIWAL, VARINDER
Diaz, Jose
Dillon, Christopher
DILLON, WILLIAM
Dimare, Gina
Dougherty, Ayah
Doyle, Diane
Drayton, Raymond S
Dubil, David
Dubil, Heather
DULAC, LOVORKA
Dull, Lindsey

Duncan, Ayanna
Eavis, Jessica
Epstein, Paula
Everett, Richard
Faherty, Bridget
Farooq, Aisha
Fields, Shalil
Fisher, Yvonne M
Floody, Joseph
Flowers, Tony
Franklin, Anthony James
Franklin, Dominic
Galvan, Christopher
Gandhi, Karmendra
Gans, Amoni
Garcia, Khadijah
Garcia, Maranda
Garzia, Dante
George, Biju
George, Binu
George, Joel
george, neethu anna
George, Suja
Getsinger, Brandon
Ghouri, Jamal
Giesen, Mark D
Giglia, Allan
Gilles, Denilia
Giovannucci, Michelle S.
Githens, Carl Leslie
Goncalves, Monica
Gondalia, Rushabh
Gonzalez, Aurea N
Gonzalez, Bryan
Gonzalez, Jared
Gonzalez, Maria J
Gonzalez, Pricilla
Goodmond, China
Goonewardene, Kumar A
Graham, Oonea
Grauvogel, John
Gray, Diane
Green, Chrystal
Groves, Samantha
Guivas Fabery, Joscar Emmanuel
Gutierrez, Milagros
Guzik, Mariusz
Guzman, Tanisha
Hall, Albert D
HALL, AMINAH
Hall, Bradlee
Hamilton, Kayla
Hampton, Jason
Hankinson, Nathan

Name in Reporting Display Format
Abdur- Rahman, Azizah
Abrams, Mark
Acosta, Miguel
Adams, Tanya
Adorno, Ivette
Adu, Oluwasegun
Akanda, Nashita
Ali, Brianna
Ali, Elizabeth
Allison, Shaurice
Almonte, Junior
Amin, Nisha
Andrews, Candice
Angelo, Denise Ann
Anil, Shyni
Antony, Jackson
Aponte, Bianca Marie
Arcos, Cesar
Ariza, Kassandra
Arroyo, Frances
Arroyo, Rosemary
Azadi, Parnian
Baby, Beena
Bader, Eric
Bah, Hadja
Bahama, Badiaa
Bame, Ema
Barilla, Erica Habel
Barry, Ebony
Bates, Bryan
Bates, William K
Bauman, William Edward
Begolli, Elda
Bell, Everett M
Benny, Binil
Bergman, Bianca
Biju, Blesson
Bizuk, Mark
Blake, Michael James
Blanton, Christopher
Blyler, Jessica
Bolton, Jalam
Bonilla, Jose
Bornaschella, Gaetano
Bosenko, Vitaliy
Boyle, Valerie
Brandao, Rui
Brooks, K'Mari
Brown, Dave
Brown, Diane
Brown, Tyherea
Brown-Watson, Nakuis

Hanna, Ashley
Harker, Sylvia
Harrison, Kenton
Haut, Jonathan Brooks
Hawk, Michael
Hays, Ami
Hazali, Amiri
Hazizi, Lindita
Heinisch, Louis Fairburn
Hernandez, Laura
Hernandez-Pagan, Awilda
Hidi, Eric
Howell, Joseph M
Howell, Tyrik
Hsu, Karen
Hull, James
Hussie, Terence
Hynes, Debora Louise
Idowu, Adedoyin
Issac, Shilz Sandu
Jackson, Christina
Jackson, Lakesha E
Jackson, Travis
Jadico, Michelle
James-Bellessis, Chante
Jantos, Daniel
Jarnagin, Hope
Jean, Nesly
Jenkins, Anajah
Jenkins, emani
Jennings, Heidi R
Johnson, Ashley
Johnson, Chyna
Johnson, Jerin
Kafi, Ifteajul
Kao, Kaitlyn
Keil, William
Kejariwal, Rohini
Kelley, Heather
Kellum, Damon
KIM, STEVE
Kirwin, Joanne
Knudsen, Hannah
Kopay, Michael
Kurian, Priya
Kurian, Shaji
Lad, Chetna
Lam, Hoa Kim
Laporte, Paula N
Laude, Rocen
Le, James
Leballeur, Jerome
Lenarduzzi, Nicholas
Charles
Liberti, Bryan

Liceaga, Janet
Lisowski, Jessica
Littner, Grace
Lo, Qiu
Long, Rashid
Longo, Frank
Lopez, Nathan
Love, Kira
Love, MeiLing
Lowery, WILLIAM
Lozada, Angel
LUCAS, ANDREA
Ludington, Jeremy
Luong, Lynne
Malczon, Kevin
Maldonado, Edwin
Maldonado, Jonathan
Mangahas, Christopher
Mangano, Sarah
Marte-Nunez, Vanessa
Martinez, Eldin
Massey, Aimee
Mateo-Cruz, Olga M
Mathew, Jayaraj
Mathies, Shean
Maw, David
May, Rany
Mayhue, Aisha
McCartney, Meghan Grace

McDonnaugh, Lauryn
McLeigh, Jacob
McMullin, Annemarie
Medina, Maelin
Melendez, Diamond
Melonashi, Albora
Mendez-Perez, Maritza
Miriam, Luz
Miske, Michele
Mitchell, Gina
Molina, Angel
Moore, Kimberly
Morales, Ramon
Morris, Donald
Mosquera, Luz
Motts, Allyson
Mulvihill, James J
Muniz, Anthony
Murcia, Angelica
Murphy, Peter
Murphy, Shawn
Murriell, Kim
Muskaj, Marjana
Narczykiewicz, Karolina
Nathan, Robert J

Navarro, Johnny
Neal, Joseph Michael
Neal, Patrick
Nguyen, Harry
Nguyen, Long
Noll, Brian
Nunez, Kiana
Nunez, Lydia
Obed, Hetal
Obed, Sanjay Reynold
Okiye, Peace
Olaleke, Olufisayo
Olanrewaju, Elizabeth
Olshanskiy, Maxim
On, Doanh
Ong, Cuong
Padolina, Ferdinand M
Palmer, Harith
Palmer, Latonya R
Parikh, Nalini
Parker, Rashawyn
Pasho, Luljeta
Patel, Hetal
Patel, Hiren
Patel, Jakesh
Patel, Janika
Patel, Kalpeshkumar
Patel, Kevin
Patel, Raveena Ishan
Patel, Sandeep
Patel, Sejalben
Patel, Tushar
Patel, Yash
Pattan, Neeraj
Paul, Janine Lindsey
Pearson, Joseph
Pena, Blanca
Pena, Rosaura
Pereira, Kelly
Pimentel Polanco, Filandia

Principe, Rachel
Pruden, James
Quinones Mendez, Victor
Manuel
Rahman, Zamiur
Ramos, Brian
Ramos, Erica
Rao, Neshma
Rao, Ragini P
Reichwein, Rex
REID, YELENA
Rice, Ikeem
Rink, Samantha
Robinson, Kimberly

Robinson, Mermastine
Rodgers, Michael J
Rodriguez, Jan
Rodriguez, Jazmine
Rodriguez, Maria R
Rodriquez, Zanya
Rondon, Ciara
Rondon, Kiara
Rosado, Olga N
Rossi, Bianca
Roy, Elsamma
Roy, Pritesh
Ruiz-Rosario, Mirna
Saint-Felix, Kevin
SALDANA, JAMES
Salvatore, Gina
Samim, Mohammad Jawid

Sampson, Breana
Sanchez, Andres
Sanchez, Arnel
Sanchez, Precious
SANJUAN, CHENCHO
Santiago, Elena
Santiago, Luis
Santiago, Moraima
Santiago, Nohelys
Santiago, Yanessa
Saraci, Valentina
Sarmiento, Monica
Saunders, Desi A
Sease, Craig L
Sen, Sindur
SEPULVEDA, VALENTIN
Serrano, Madeline
Serrano, Wanda I
Servius, Rosebentha
Shafer, Peyton
Shah, Dhara
Shah, Manish
Shah, Sangita
Shaikh, Asim Y
Shaikh, Rehanabanu
SHAJI, SHINY
Shaw, Troy T
Sheloski, Connor
Sheppy, Deandra L
Shook, Anthony
Siji, Jesy
Simion, Anca
Simmons, Montrell
Simmons-Perry, Amonnie
Singh, Jiwan
Slayton, Nadia
Sleister, Kathleen Anne

Smith, James Richardson
Smith, Kyle
Smith, Lilly
Smith, Quran
Smith, Sabrina
Staples, Randolph
Strataj, Klarita
Strickland, Marcus
Suarez, Marilyn
Taherian, Niki
Tailor, Kailash
Thomas, Allen
Thomas, Babu
THOMAS, BIBIN
Thomas, Darnelle
Thomas, Elizabeth
Thomas, Joby
Thomas, Juby
Thomas, Kathleen A
Thomas Koshy, Tresa
Thompson, Sean
Thompson, Shalonda
Thompson, Tayler
THOMPSON, TIFFANY
Titto, Christeena
Traber, James Thomas
Tracy, Conner
Trainor, Nicole
Tran, David
Travers, Cylinda T
Trendler, Stephen
Trzesniowski, Paul
Tucker, Alexus
TUTIN, MELANIE
Tyler, Alexandra
Vahora, Neelam
Valentin, Marisol
Vankar, Mukund
Varughese, Monson
VAZQUEZ, ALICIA
Vega, Lionel
Vent, Jeffrey
Vettickal Subhash, Reshma

Vijayanathan, Chelliah
Aruun
Von Der Linden, Cecelia
Wagner, Cynthia
Wagoner, Roberta
Washington, Valorie P
Watson, Angela
Weiss, Karen
Wilczynska, Katarzyna
Wildgoose, Ramona

Williams, Jacqueline Laguatan
Williams, Kellie
Williams, Sonia
Williams, Tremayne
Williams, Xaviera
Wimsatt, Lauren
Wister, Lindsay
Wlazlo, John
Wozniak, Madelyn
Xhaferi, Vjollca
Yetter, Maureen M
Yoeun, Sokha
Young, Linda M
Young, Susan
Zharri, Anita
Zissios, Dena
Zwierzchowski, Sam

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Euclid Vision Corporation

Physical Address: 45472 Holiday Dr., Suite 7

City: Sterling State: VA Zip: 20166

Mailing Address (if different from physical address): same as above

City: _____ State: VA Zip: 20166

Telephone: (703) 471-7145 Website: www.euclidlenses.com

Name of Designated Representative (DR): Mark Mercier

Licensing Company Email: Mark.mercier@euclidsys.com DR Email: Mark.mercier@euclidsys.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Euclid Vision Group

Corporation/Organization Name: Euclid Vision Corporation

Mailing Address: 45472 Holiday Dr.. Suite 7

City: Sterling State: VA Zip: 20166

Telephone: (703) 471-7145 Email: Mark.mercier@euclidsys.com

Contact Person Name: Mark Mercier

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment J	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Euclid Vision Corporation

Facility Name

Mark Mercier Mark E. Mercier

Print Name of Authorized Person Submitting Application

Mark E M.

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

12/3/2024

Date

Board Use Only	Date Received: 1/2/25	Amount: $100 - ck 1600

Attachment A

Nature of Business

Euclid Vision Corporation "Euclid" is a manufacturer of prescription devices (contact lenses). Euclid will physically manufacture and ship its product. Enclosed is a list of product the company will distribute.

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
EUCLID VISION CORPORATION
45472 Holiday Drive
Suite 7
Sterling, VA 20166
Registration Number: 3014175039
FEI Number*: 3014175039
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Euclid Vision Corporation
45472 Holiday Drive
Sterling, VA US 20166
Owner/Operator Number: 10056673

Official Correspondent:
Sandra Freitez
45472 Holiday Drive
Sterling, VA 20166
Phone: 1-703-4717145-242

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 04/15/2024
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Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

verified M,H 1/10/25

Attachment D

Corporation Information

Corporate Officer:

Linda Chang
Interim CEO

Board of Director:

Colm O'Connell

Parent Company:

Euclid Vision Group
Ownership: 100%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "EUCLID VISION CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF CONVERSION", FILED THE FIFTH DAY OF AUGUST, A.D. 2020, AT 5:26 O`CLOCK P.M.

CERTIFICATE OF INCORPORATION, FILED THE FIFTH DAY OF AUGUST, A.D. 2020, AT 5:26 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "EUCLID VISION CORPORATION".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "EUCLID VISION CORPORATION" WAS INCORPORATED ON THE FIFTH DAY OF AUGUST, A.D. 2020.

Jeffrey W. Bullock, Secretary of State

3387066 8315

SR# 20241754556

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

Authentication: 203368202

Date: 04-30-24

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3387066 8315

SR# 20241754556

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

Authentication: 203368202

Date: 04-30-24

Virginia Department of Health Professions
An official website Here's how you know

Find a Commonwealth Resource

Virginia Department of Health Professions
License Lookup

Current as of 03/20/2025 14:29

License Information

License Number	0216000208
Occupation	Warehouser
Name	Euclid Vision Corporation
Address	Brian Norman 45472 Holiday Dr., Suite 7 Sterling, VA 20166
Initial License Date	10/04/2024
Expire Date	02/28/2026
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

** "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/04/2025

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

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

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED Euclid Vision Corporation dba Euclid Systems Corporation 45472 Holiday Drive Suite 7 Sterling, VA 20166	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Federal Insurance Company — 20281 INSURER B: Travelers Indemnity Company of America — 25666 INSURER C: Lloyd's — B7874 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W38062380 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			36090854	03/01/2025	03/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ $ $ $ $ $ $	1,000,000 1,000,000 10,000 1,000,000 2,000,000
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73649396	03/01/2025	03/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ $ $ $ $	1,000,000
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			56726873	03/01/2025	03/01/2026	EACH OCCURRENCE AGGREGATE [ ]	$ $ $	5,000,000 5,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? [ ] Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB-5P966235-25-I6-G	01/24/2025	01/24/2026	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $	 1,000,000 1,000,000 1,000,000
C	Products Liability			LSR-PCO-00597-25	03/01/2025	03/01/2026	Policy Aggregate Retention	$5,000,000 $10,000	

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

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Debra M Deva

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 6213038697

Application/License No. NV20011396335

Euclid Vision Corporation (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 45472 Holiday Dr., Suite 7, Sterling, VA 20166 (Address of Applicant/Principal), as PRINCIPAL, and United States Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 305 MADISON AVENUE, MORRISTOWN, NJ 07960 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 11/26/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of November, 20 24.

APPLICANT/PRINCIPAL
Euclid Vision Corporation

Authorized Representative

SURETY COMPANY
United States Fire Insurance Company

Surety Company's Representative

Michelle Anne McMahon, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Blair Housley

Witness

SIGNED and SEALED in the presence of:

Witness Ashley Alexis

Witness Sarah Fistner

Witness Rhonda Tischofer

Countersigned by:

Nevada Resident Agent
Jonathan Raymond Gleason
NV Non-Resident License Number: 3816389

POWER OF ATTORNEY
UNITED STATES FIRE INSURANCE COMPANY
PRINCIPAL OFFICE - MORRISTOWN, NEW JERSEY

79560

KNOW ALL MEN BY THESE PRESENTS: That United States Fire Insurance Company, a corporation duly organized and existing under the laws of the state of Delaware, has made, constituted and appointed, and does hereby make, constitute and appoint:

Gentry Stewart, Kathryn Pryor, Michelle Anne McMahon, Joshua Sanford, Nicholas Turecamo, Sam E. Begun, Melissa J. Stanton, Robyn Salley, Rebecca M. Josephson, Jennifer Godere, Jonathan Gleason, Doritza Mojica, Nicholas Miller, Sarah Murtha, Connor Wolpert, Richard Hackner, Kristopher Pisano

each, its true and lawful Attorney(s)-In-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver: Any and all bonds and undertakings of surety and other documents that the ordinary course of surety business may require, and to bind United States Fire Insurance Company thereby as fully and to the same extent as if such bonds or undertakings had been duly executed and acknowledged by the regularly elected officers of United States Fire Insurance Company at its principal office, in amounts or penalties: **Unlimited**

This Power of Attorney limits the act of those named therein to the bonds and undertakings specifically named therein, and they have no authority to bind United States Fire Insurance Company except in the manner and to the extent therein stated.

This Power of Attorney is granted pursuant to Article IV of the By-Laws of United States Fire Insurance Company as now in full force and effect, and consistent with Article III thereof, which Articles provide, in pertinent part:

Article IV, Execution of Instruments - Except as the Board of Directors may authorize by resolution, the Chairman of the Board, President, any Vice-President, any Assistant Vice President, the Secretary, or any Assistant Secretary shall have power on behalf of the Corporation:

(a) to execute, affix the corporate seal manually or by facsimile to, acknowledge, verify and deliver any contracts, obligations, instruments and documents whatsoever in connection with its business including, without limiting the foregoing, any bonds, guarantees, undertakings, recognizances, powers of attorney or revocations of any powers of attorney, stipulations, policies of insurance, deeds, leases, mortgages, releases, satisfactions and agency agreements;
(b) to appoint, in writing, one or more persons for any or all of the purposes mentioned in the preceding paragraph (a), including affixing the seal of the Corporation.

Article III, Officers, Section 3.11, Facsimile Signatures. The signature of any officer authorized by the Corporation to sign any bonds, guarantees, undertakings, recognizances, stipulations, powers of attorney or revocations of any powers of attorney and policies of insurance issued by the Corporation may be printed, facsimile, lithographed or otherwise produced. In addition, if and as authorized by the Board of Directors, dividend warrants or checks, or other numerous instruments similar to one another in form, may be signed by the facsimile signature or signatures, lithographed or otherwise produced, of such officer or officers of the Corporation as from time to time may be authorized to sign such instruments on behalf of the Corporation. The Corporation may continue to use for the purposes herein stated the facsimile signature of any person or persons who shall have been such officer or officers of the Corporation, notwithstanding the fact that he may have ceased to be such at the time when such instruments shall be issued.

IN WITNESS WHEREOF, United States Fire Insurance Company has caused these presents to be signed and attested by its appropriate officer and its corporate seal hereunto affixed this 28th day of September, 2021.

UNITED STATES FIRE INSURANCE COMPANY

Matthew E. Lubin, President

State of New Jersey}
County of Morris }

On this 28th day of September, 2021, before me, a Notary public of the State of New Jersey, came the above named officer of United States Fire Insurance Company, to me personally known to be the individual and officer described herein, and acknowledged that he executed the foregoing instrument and affixed the seal of United States Fire Insurance Company thereto by the authority of his office.

MELISSA H. D'ALESSIO
NOTARY PUBLIC OF NEW JERSEY
Commission # 50125833
My Commission Expires 4/7/2025

Melissa H. D'Alessio (Notary Public)

I, the undersigned officer of United States Fire Insurance Company, a Delaware corporation, do hereby certify that the original Power of Attorney of which the foregoing is a full, true and correct copy is still in force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal of United States Fire Insurance Company on the 26th day of November 20 24

UNITED STATES FIRE INSURANCE COMPANY

Michael C. Fay, Senior Vice President

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Euclid Vision Corporation MDEG License # (if applicable) _____

Physical Address 45472 Holiday Dr., Suite 7

City Sterling State VA Zip 20166

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 703-471-7145 Website www.euclidlenses.com

Licensing Company Email Mark.mercier@euclidsys.com

Section 2: Personal Information

First Mark Middle Edward Last Mercier

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

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

Mailing Addres[redacted]

City Sterling State VA Zip [redacted]

Telephon[redacted] Email Mark.mercier@euclidsys.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Central Connecticut State University		9/1975 - 5/1977	
Address	**City**	**State**	**Zip**
1615 Stanley St.	New Britain	CT	06050
Diploma/Degree obtained, if any			
B.S. Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
Norwich Regional Technical School		9/1968 - 5/1972	
Address	**City**	**State**	**Zip**
7 Mahan Dr.	Norwich	CT	06360
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - present	[redacted]	Brambleton	VA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
11/20 - 11/21		Franklin	TN	
From - To (MM/YY – MM/YY)		City	State	
03/19 - 11/20		Franklin	TN	
From - To (MM/YY – MM/YY)		City	State	
03/15 - 11/20		Franklin	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Euclid Vision Corporation			2/2022 - Current
Business Address	**City**	**State**	**Zip**
45472 Holiday Dr, Suite 7	Sterling	VA	20166
Phone	**Title**	**Number of Employed Hours**	
(703) 471-7145	Executive Vice President of Operational Excellence	~4,640	
Description of Duties			
Manage the manufacturing facilities and process for RGP contact lens that manage myopia, RGP Scleral Lenses and development of polymers that are used to manufacture RGP contact lens			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Mark Mercier, **certify that as the MDEG Administrator for**

_____,

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

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

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

Mark E. Mercier
Print Name (First, Last)

Mark E. Mercier
Original Signature (electronic, copies or stamps not accepted)

12/3/24
Date

Board Use Only	Date Received: 1/2/25

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Euclid Vision Corporation

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 45472 Holiday Dr., Suite 7

City Sterling State VA Zip 20166

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone (703) 471-7145 Website www.euclidlenses.com

Licensing Company Email Mark.mercier@euclidsys.com

Section 2: Personal Information

First Mark Middle Edward Last Mercier

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

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

Mailing Address [redacted]

City Sterling State VA Zip [redacted]

Telephone [redacted] Email Mark.mercier@euclidsys.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Central Connecticut State University		9/1975 - 5/1977	
Address	**City**	**State**	**Zip**
1615 Stanley St.	New Britain	CT	06050
Diploma/Degree obtained, if any			
B.S. Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
Norwich Regional Technical School		9/1968 - 5/1972	
Address	**City**	**State**	**Zip**
7 Mahan Dr.	Norwich	CT	06360
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - present	[redacted]	Brambleton	VA	[redacted]
From - To (MM/YY – MM/YY) 11/20 - 11/21		Franklin	TN	
From - To (MM/YY – MM/YY) 03/19 - 11/20		Franklin	TN	
From - To (MM/YY – MM/YY) 03/15 - 11/19		Franklin	TN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY) ~4,640	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Euclid Vision Corporation			2/2022 - Current	
Business Address		**City**	**State**	**Zip**
45472 Holiday Dr, Suite 7		Sterling	VA	20166
Phone	**Title**		**Number of Employed Hours**	
(703) 471-7145	Executive Vice President of Operational Excellence		~4,640	
Description of Duties				
Manage the manufacturing facilities and process for RGP contact lens that manage myopia, RGP Scleral Lenses and development of polymers that are used to manufacture RGP contact lens.				

Business Name			From - To (MM/YY – MM/YY)	
Euclid Vision Corporation			2/2022 - 4/2022	
Business Address		**City**	**State**	**Zip**
45472 Holiday Dr, Suite 7		Sterling	VA	20166
Phone	**Title**		**Number of Employed Hours**	
(703) 471-7145	VP of Operations and Technology		~480	
Description of Duties				
Responsible for engineering, planning, manufacturing and distribution of OrthoK contact lenses.				

Business Name			From - To (MM/YY – MM/YY)	
Euclid Vision Corporation			9/2021 - 2/2022	
Business Address		**City**	**State**	**Zip**
45472 Holiday Dr, Suite 7		Sterling	VA	20166
Phone	**Title**		**Number of Employed Hours**	
(703) 471-7145	Sr Director of Manufacturing		~960	
Description of Duties				
Responsible for engineering, planning, manufacturing and distribution of OrthoK contact lenses.				

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

N/A

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Mark Mercier, **certify that as the designated representative for**

Euclid Vision Corporation,

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

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

Mark Mercier

Print Name (First, Last)

Mark E. Mercier

Original Signature (electronic, copies or stamps not accepted)

12/3/2024

Date

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

Mark Mercier

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/3/2024

Date

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

State of Virginia, ss. County of Fairfax

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

Original Signature

12/3/24

Date

Subscribed and Sworn to before me this 3 day of December.

Notary Public Signature

SARAH MARIE FISTNER
NOTARY PUBLIC • REG. # 8065211
Commonwealth of Virginia
My Commission Expires 06/30/2027

(Seal)

Active Employee Listing

EE Number	ployee Name (Last Suffix, First	Employee Email	Org Level 2	Company	Location
000002	Alvarez, Daniel A.	[redacted]	Corporate	Euclid Vision Corporation	HQ-VA
000005	Cantolina, Abbey E.		Corporate	Euclid Vision Corporation	HQ-VA
000009	Dabu, Daniel D.		Corporate	Euclid Vision Corporation	HQ-VA
000023	Hernandez Rodriguez, Jose		Corporate	Euclid Vision Corporation	HQ-VA
000029	Norman, Brian		Corporate	Euclid Vision Corporation	HQ-VA
000038	Young, Virginia A.		Corporate	Euclid Vision Corporation	HQ-VA
000041	Lindsey, Samantha S.		Corporate	Euclid Vision Corporation	HQ-VA
000096	Warren, Randec D.		Corporate	Euclid Vision Corporation	HQ-VA
000128	Rodriguez, Maria J.		Corporate	Euclid Vision Corporation	HQ-VA
000142	Azanaw, Abel		Corporate	Euclid Vision Corporation	HQ-VA
000153	Guewo Simo, Annette		Corporate	Euclid Vision Corporation	HQ-VA
000157	Sasaki, Akemi		Corporate	Euclid Vision Corporation	HQ-VA
000164	Adefowoju, Ifedayo		Corporate	Euclid Vision Corporation	HQ-VA
000166	Getachew, Sara		Corporate	Euclid Vision Corporation	HQ-VA
000168	Robinson, Maurice		Corporate	Euclid Vision Corporation	HQ-VA
000172	Chaudhary, Sadikshya		Corporate	Euclid Vision Corporation	HQ-VA
000173	Zapata, Tirsa		Corporate	Euclid Vision Corporation	HQ-VA
000186	Hernandez, Wendy		Corporate	Euclid Vision Corporation	HQ-VA
000189	Pokhrel, Sangita		Corporate	Euclid Vision Corporation	HQ-VA
000190	Davila, Margarita		Corporate	Euclid Vision Corporation	HQ-VA
000192	Pokhrel, Subasmani		Corporate	Euclid Vision Corporation	HQ-VA
000197	Wohlschlag, Jonathan C.		Corporate	Euclid Vision Corporation	HQ-VA
000208	Beale, Jacque A.		Corporate	Euclid Vision Corporation	HQ-VA
000214	Padilla, Maria Theresa L.		Corporate	Euclid Vision Corporation	HQ-VA
000217	Rajdhami, Abhishek		Corporate	Euclid Vision Corporation	HQ-VA
000218	Canales, Vanesa E.		Corporate	Euclid Vision Corporation	HQ-VA
000233	Padilla, Mary Jane		Corporate	Euclid Vision Corporation	HQ-VA
000239	Shrestha, Rashila		Corporate	Euclid Vision Corporation	HQ-VA
000244	Kafle, Sita		Corporate	Euclid Vision Corporation	HQ-VA
000250	Bhattarai, Tara		Corporate	Euclid Vision Corporation	HQ-VA
000252	Nakarmi, Rajendra		Corporate	Euclid Vision Corporation	HQ-VA
000259	Shrestha, Shakuntala		Corporate	Euclid Vision Corporation	HQ-VA
000263	Brar, Harjeet K.		Corporate	Euclid Vision Corporation	HQ-VA
000265	Dahal, Pawan		Corporate	Euclid Vision Corporation	HQ-VA
000269	Khairnar, Rishikesh		Corporate	Euclid Vision Corporation	HQ-VA
000272	Malnegro, Lilibeth		Corporate	Euclid Vision Corporation	HQ-VA
000274	Upadhaya, Dipa		Corporate	Euclid Vision Corporation	HQ-VA
000276	Shrestha, Sabin		Corporate	Euclid Vision Corporation	HQ-VA
000277	Upreti, Tara		Corporate	Euclid Vision Corporation	HQ-VA
000286	Ball, Ivan		Corporate	Euclid Vision Corporation	HQ-VA
000289	Lozano Avila, Carlos G.		Corporate	Euclid Vision Corporation	HQ-VA
000297	Zewdie, Amsale		Corporate	Euclid Vision Corporation	HQ-VA
000298	Mercier, Mark E.		Corporate	Euclid Vision Corporation	HQ-VA
000302	Sanders, Rosario		Corporate	Euclid Vision Corporation	HQ-VA
000306	Rivera, Amy N.		Corporate	Euclid Vision Corporation	HQ-VA
000307	Khatri, Om Kumari		Corporate	Euclid Vision Corporation	HQ-VA
000309	Magdamit, Mely L.		Corporate	Euclid Vision Corporation	HQ-VA
000314	Rai, Sabita		Corporate	Euclid Vision Corporation	HQ-VA
000322	Chaudhry, Laraib		Corporate	Euclid Vision Corporation	HQ-VA
000326	Mead, Andrew S.		Corporate	Euclid Vision Corporation	HQ-VA
000335	Cao, Bo		Corporate	Euclid Vision Corporation	HQ-VA

000336	Saifulmalook, Ata M.	[redacted]	Corporate	Euclid Vision Corporation	HQ-VA
000346	Rana, Isha		Corporate	Euclid Vision Corporation	HQ-VA
000351	Islam, MD M.		Corporate	Euclid Vision Corporation	HQ-VA
000352	Yousufzai, Ahmad Uzair		Corporate	Euclid Vision Corporation	HQ-VA
000362	Sarkar, Furingka		Corporate	Euclid Vision Corporation	HQ-VA
000364	Gable, Debra		Corporate	Euclid Vision Corporation	HQ-VA
000372	Rashidi, Abdul S.		Corporate	Euclid Vision Corporation	HQ-VA
000375	Bhattarai Khatri, Sanu K.		Corporate	Euclid Vision Corporation	HQ-VA
000378	Lins, Stephanie H.		Corporate	Euclid Vision Corporation	HQ-VA
000379	Liu, Zhuoshi G.		Corporate	Euclid Vision Corporation	HQ-VA
000380	Homs Jr., Angel L.		Corporate	Euclid Vision Corporation	HQ-VA
000381	Vance, Matthew A.		Corporate	Euclid Vision Corporation	HQ-VA
000383	Adane, Destayehu A.		Corporate	Euclid Vision Corporation	HQ-VA
000387	Zarifi, Ahmad M.		Corporate	Euclid Vision Corporation	HQ-VA
000388	Merzad, Shukria		Corporate	Euclid Vision Corporation	HQ-VA
000389	Alizada, Fatima		Corporate	Euclid Vision Corporation	HQ-VA
000390	Rahmani, Najibullah		Corporate	Euclid Vision Corporation	HQ-VA
000399	Roman, Marangelli		Corporate	Euclid Vision Corporation	HQ-VA
000403	Khattak, Salahuddin K.		Corporate	Euclid Vision Corporation	HQ-VA
000404	Appiah, David B.		Corporate	Euclid Vision Corporation	HQ-VA
000408	Gurung, Indira		Corporate	Euclid Vision Corporation	HQ-VA
000415	Marquette, Abigail		Corporate	Euclid Vision Corporation	HQ-VA
000417	Neupane, Niru		Corporate	Euclid Vision Corporation	HQ-VA
000422	O'Connell, John L.		Corporate	Euclid Vision Corporation	HQ-VA
000423	Ransom, Leighann		Corporate	Euclid Vision Corporation	HQ-VA
000426	Jalali, Yalda		Corporate	Euclid Vision Corporation	HQ-VA
000428	Santillan Orosco, Gonzalo J.		Corporate	Euclid Vision Corporation	HQ-VA
000436	Qaderi, Sanam		Corporate	Euclid Vision Corporation	HQ-VA
000437	Ali, Aziza		Corporate	Euclid Vision Corporation	HQ-VA
000439	Fishbein, Sam		Corporate	Euclid Vision Corporation	HQ-VA
000452	Sadat, Sayed F.		Corporate	Euclid Vision Corporation	HQ-VA

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

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

Section 1: General Information

Facility Name: KalVista Pharmaceuticals, Inc.

Physical Address: 55 Cambridge Pkwy, Ste 901E

City: Cambridge State: MA Zip: 02142

Mailing Address (if different from physical address): 55 Cambridge Pkwy, Ste 900

City: Cambridge State: MA Zip: 02142

Telephone: 857-999-0075 Website: www.kalvista.com

Name of Designated Representative (DR): Douglas Tennison

Licensing Company Email: usstatelicensing@kalvista.com DR Email: ktennison@kalvista.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others: Specialty Pharmacies		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within the last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): N/A

Corporation Name: KalVista Pharmaceuticals, Inc.

Mailing Address: 55 Cambridge Pkwy, Ste 900

City: Cambridge State: MA Zip: 02142

Telephone: 857-999-0075 Email: usstatelicensing@kalvista.com

Contact Person Name: Douglas Tennison

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Nicole Sweeney
Original Signature (electronic, copies or stamps not accepted)

2/11/25
Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

KalVista Pharmaceuticals, Inc.
Facility Name

Nicole Sweeny
Print Name of Authorized Person Submitting Application

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

2/11/25
Date

Board Use Only	Date Received: 3/6/25	Amount: $1000 ck 3185

KalVista
Pharmaceuticals

Description of Operations

KalVista Pharmaceuticals, Inc. is a virtual manufacturer. KalVista Pharmaceuticals, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed by their Third-Party Logistics Provider, Cardinal Health SPS to, who is licensed to ship pharmaceutical products into your state to Specialty Pharmacies.

Contract Manufacturer Information:
We are using the following contract manufacturers to produce our product:

CMO #1
Almac Pharma Services Limited
Seagoe Industrial Estate
Portadown
Craigavon, Northern Ireland
United Kingdom BT63 5QD
FDA Establishment Number: 3004444888

Contact Person: Ian Markwell
Contact Number: +44 (0) 28 3836 3363

CMO #2
Catalent Nottingham Limited
8 Orchard Place
Nottingham Business Park
Nottingham, United Kingdom NG8 6PX
FDA Establishment Number: 3005680952

Contact Person: Julia Hocking
Contact Number: +44(0)1158718888

CMO #3
Zach System S.A.
Zone Industrielle Croix Cadeau
Avrille, France 49240
FDA Establishment Number: 3002808164

Contact Person: Sophie Vechembre
Contact Number: +33 2 41966173

Almac Pharma Services Limited, Catalent Nottingham Limited, and Zach System S.A. manufacture KalVista Pharmaceuticals, Inc.'s product and packages finished product. At no time does Almac Pharma Services Limited, Catalent Nottingham Limited, or Zach System S.A own the product, contract with KalVista Pharmaceuticals, Inc.'s customers, invoice, nor sell a KalVista Pharmaceuticals, Inc. product. KalVista Pharmaceuticals, Inc.'s products are not Controlled Substances.

Labeler Code:
82928

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health SPS acts as KalVista Pharmaceuticals, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of KalVista Pharmaceuticals, Inc.'s product-throughout the United States. Cardinal Health SPS's address is:

Cardinal Health SPS
501 Mason Rd
La Vergne, TN 37086
c/o Emily Siegrist- 615.287.8977

KalVista Pharmaceuticals, Inc., has 170 employees globally with 40 working on site during normal business hours.

KalVista Pharmaceuticals, Inc.'s hours of operation are 9:00 am – 5:30pm EST Monday through Friday.

KalVista Pharmaceuticals, Inc.'s sales records are stored at Cardinal Health SPS.

KalVista Pharmaceuticals, Inc.'s facility square footage is 8406 .

From: edrls@fda.hhs.gov
To: Peter Parsonson
Subject: Labeler Code Request Approved
Date: Monday, August 8, 2022 10:37:39 AM

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eDRLS - Electronic Drug Registration & Listing System

Current Date: 08-AUG-2022
Labeler DUNS: 156762366
Labeler Name: KalVista Pharmaceuticals, Inc.
Labeler Code Assigned: 82928

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Company Information

Company Name: KalVista Pharmaceuticals, Inc.
Address: 55 Cambridge Pkwy, Ste 901E
City, State, Zip: Cambridge, Mass 02142
Phone: 857-999-0075
Website: https://www.kalvista.com/
E-mail: usstatelicensing@kalvista.com

FEIN: 20-0915291
State of Formation: Delaware
Date Incorporated: 3/26/2024
File Number: 3782773

Ownership Information

KalVista Pharmaceuticals, Inc. is Publicly Traded company on the NASDAQ stock exchange under the symbol KALV.

Officers

Douglas Keith Tennison, VP, Market Access
Business Address: 55 Cambridge Parkway, Suite 901E, Cambridge, Mass 02142
Business Phone: 857-999-0075

Nicole Sweeny
Business Address: 55 Cambridge Pkwy, 9th Floor, Cambridge Mass 02142
Business Phone: 857-999-0075

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "KALVISTA PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "KALVISTA PHARMACEUTICALS, INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF MARCH, A.D. 2004.

Jeffrey W. Bullock, Secretary of State

3782773 8300

SR# 20243132440

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

Authentication: 204163370

Date: 08-14-24

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

KalVista Pharmaceuticals, Inc.
55 Cambridge Pkwy, Ste 901E
Cambridge, MA 02142

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200107

Type: Virtual Manufacturer

Issue Date: 12/09/2024

Expiration Date: 12/09/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

Tel: 617-624-6000
www.mass.gov/dph

MAURA T. HEALEY
Governor
KIMBERLEY DRISCOLL
Lieutenant Governor

KATHLEEN E. WALSH
Secretary
ROBERT GOLDSTEIN, MD, PhD
Commissioner

Verification of Licensure

03/11/2025

To Whom It May Concern:

The organization named below has received the following in the Commonwealth of Massachusetts:

Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration

Name of Organization: KalVista Pharmaceuticals, Inc.

Registration Number: VIR200107
Registration Status: Current
Issue Date: 12/09/2024
Expiration Date: 12/09/2025
Disciplinary Actions: There are no disciplinary actions against this registration.

Registration verification may be obtained at http://checkahealthlicense.mass.gov/. The information provided in this "Verification" is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the "Verification." Disciplinary status is defined as voluntary surrender, revocation, suspension or probation of a license. The "Verification" does not include information about the existence, absence, or status of complaints. To request such information, please submit a public record request to publicrecordsadmin@massmail.state.ma.us.

Traci Westgate

Traci Westgate
Director

3ebc9e26-3693-4562-b680-428ff83976c7

SURETY SOLUTIONS
A Gallagher Company

Thank you for your bond purchase and for choosing

Surety Solutions, a Gallagher Company.

Bond Number: AM3276942	Writing Company: Platte River Insurance Company
Effective Date: 12/26/2024	Expiration Date: 12/26/2025

The enclosed packet contains all the documents required for your bond.

To ensure your bond is properly submitted and accepted by the entity requiring the bond, please follow these steps:

1. Verify the accuracy of the documents.

   To address any corrections, please contact us at (866) 722-9239.

2. Sign the bond.

   Certain bonds will require notary or witness signatures on the bond form itself, or in an attached document (included in the packet).

3. Send the bond to the address listed below (Obligee).

   Be sure to include all required documents, including the bond form, any additional pages or worksheets, notary acknowledgement and power of attorney (POA).

Mississippi Board of Pharmacy
6360 I-55 North Suite 400
Jackson MS 39211

The included invoice is for your records only and should not be sent to the Obligee.

Surety Solutions, a Gallagher Company
4285 Commercial St. SE Suite 110
Salem, OR 97302
(866) 722-9239
http://www.suretysolutions.com

NOTICE OF DISCLOSURES

Principal Name & Address
KalVista Pharmaceuticals, Inc.
55 Cambridge Parkway Suite 901E
Cambridge MA 02142
Ph: Fax:

Surety Bond Description: Mississippi Pharmaceutical Drug Facility Bond
Surety Name: Platte River Insurance Company
Bond Number: AM3276942
Coverage Term: 12/26/2024 - 12/26/2025
Bond Premium: $1,500.00
Commission: $600.00

Type of Bond
$100,000.00 Mississippi Pharmaceutical Drug Facility Bond

Obligee Name & Address
Mississippi Board of Pharmacy
6360 I-55 North Suite 400
Jackson MS 39211

Cancellation Provision: Varies – see bond form.

Carrier Ratings and Admitted Status

Proposed Insurance Companies	A.M. Best's Rating
Platte River Insurance Company	A IX

* Best's Credit Ratings™ reproduced herein appear under license from A.M. Best and do not constitute, either expressly or impliedly, an endorsement of Gallagher's service or its recommendations. A.M. Best is not responsible for transcription errors made in presenting Best's Credit Ratings™. Best's Credit Ratings™ are proprietary and may not be reproduced or distributed without the express written permission of A.M. Best.
* A Best's Financial Strength Rating is an independent opinion of an insurer's financial strength and ability to meet its ongoing insurance policy and contract obligations. It is not a warranty of a company's financial strength and ability to meet its obligations to policyholders. Best's Credit Ratings™ are under continuous review and subject to change and/or affirmation. For the latest Best's Credit Ratings™ and Guide to Best's Credit Ratings, visit the A.M. Best website at http://www.ambest.com/ratings.

** If coverage placed with a non-admitted carrier, it is doing business in the state as a surplus lines or non-admitted carrier, and is neither subject to the same regulations as an admitted carrier nor do they participate in any state insurance guarantee fund.

Gallagher companies make no representations and warranties concerning the solvency of any carrier, nor does it make any representation or warranty concerning the rating of the carrier which may change.

Additional Fees: The following non-refundable fees may be charged during the term of the bond
$30 Rider Fee – Physical Riders
$15 Rider Fee – Electronic Riders
$30 Duplicate Originals Request
$30 Additional Physical Document Issuance
$30 Reinstatement Fee
$30 Overnight Shipping Fee
$50 ERISA Bond Administration Fee
$100 RIA Fidelity Policy Administration Fee

Cancellations: Bond forms vary widely with respect to cancellation provisions. Please refer to your particular form for specific provisions and contact us with any questions or concerns.

Notwithstanding anything else contained in this Proposal, Gallagher is not required to provide Services to you if Gallagher reasonably considers that to do so would put Gallagher in breach of, or would expose Gallagher or its affiliates to fines, penalties or sanctions under any laws, regulations, professional rules or, in Gallagher's sole opinion, you have breached a term/the terms of the Policies. In such circumstances, Gallagher will be entitled to terminate its Services with immediate effect. In the event that Gallagher exercises its right to terminate its Services with immediate effect, Gallagher will not be responsible or liable to you for any direct or indirect loss which you or any other party may suffer as a result.

Please be aware that Gallagher is generally restricted from providing broking, claims handling or other services that relate to Cuba and Iran, including due to significant difficulties in processing payments and other commercial and reputational considerations.

Compensation Disclosure

1. Gallagher Companies are primarily compensated from the usual and customary commissions, fees or, where permitted, a combination of both, for brokerage and servicing of insurance policies, annuity contracts, guarantee contracts and surety bonds (collectively "insurance coverages") handled for a client's account, which may vary based on market conditions and the insurance product placed for the client.

2. In placing, renewing, consulting on or servicing your insurance coverages, Gallagher companies may participate in contingent and supplemental commission arrangements with intermediaries and insurance companies that provide for additional compensation if certain underwriting, profitability, volume or retention goals are achieved. Such goals are typically based on the total amount of certain insurance coverages placed by Gallagher with the insurance company, not on an individual policy basis. As a result, Gallagher may be considered to have an incentive to place your insurance coverages with a particular insurance company. If you do not wish to have your commercial insurance placement included in consideration for additional compensation, contact your producer or service team for an Opt-out form.

3. Gallagher Companies may receive investment income on fiduciary funds temporarily held by them, or from obtaining or generating premium finance quotes, unless prohibited by law.

4. Gallagher Companies may also access or have an ownership interest in other facilities, including wholesalers, reinsurance intermediaries, captive managers, underwriting managers and others that act as intermediaries for both Gallagher and other brokers in the insurance marketplace some of which may earn and retain customary brokerage commission and fees for their work.

If you have specific questions about any compensation received by Gallagher and its affiliates in relation to your insurance placements, please contact your Gallagher representative for more details.

In the event you wish to register a formal complaint regarding compensation Gallagher receives from insurers or third-parties, please contact Gallagher via e-mail at Compensation_Complaints@ajg.com or by regular mail at:

Chief Compliance Officer
Gallagher Global Brokerage
Arthur J. Gallagher & Co.
2850 Golf Rd.
Rolling Meadows, IL 60008

MISSISSIPPI BOARD OF PHARMACY

6360 1-55 North, Suite 400
Jackson, MS 39211
Office: 601-899-8880
Fax: 601-899-8851
www.mbp.state.ms.us

PHARMACEUTICAL DRUG FACILITY SURETY BOND

Surety Bond No. AM3276942

KalVista Pharmaceuticals, Inc. (Applicant's/Principal's name as it appears on the permit), doing business as a pharmaceutical drug facility, whose address for purposes of service of process is 55 Cambridge Parkway Suite 901E Cambridge, MA 02142, as Principal, and Platte River Insurance Company (Surety's name), a corporation organized under the laws of the State of NE and authorized to transact a general surety business in the State of Mississippi, whose address for purposes of service of process is 1600 Aspen Commons Suite 300 Middleton, WI 53562 as Surety, are indebted and held firmly bound to the State of Mississippi and to the Mississippi Board of Pharmacy (MBP) for the sum of: (check one)

✘ One Hundred Thousand Dollars ($100,000.00)

_____ Twenty-Five Thousand Dollars ($25,000.00)

for which payment Principal and Surety bind ourselves and our legal representatives and successors, jointly and severally.

The purpose of this surety is to ensure compliance with the requirements of the Mississippi Pharmacy Practice Act, Mississippi Code Annotated §§ 73-21-71, et seq., and the rules and regulations adopted there under, and to secure payment of any administrative penalties imposed by the MBP, and any fees and costs incurred by the MBP in relation to enforcing the rules and regulations of the MBP upon the Principal's permit and which the Principal fails to pay thirty (30) days after the fine or costs become final.

This Bond is subject to the following conditions:

1. This bond and the obligation under the bond shall be deemed to run continuously and shall remain in full force and effect and the MBP may make claim against this surety bond until one year after the Principal's permit issued by the MBP ceases to be valid or until ninety (90) days after any administrative or legal proceeding which involved the Principal is concluded, including any appeal, whichever occurs later.
2. The total aggregate liability of the bond shall be limited to the amount as indicated above in this document.

3. A claim by the MBP may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any claim shall be made payable to the Mississippi Board of Pharmacy.
4. Surety reserves the right to cancel this bond at any time upon sixty (60) days written notice by certified or registered mail to the MBP. The liability of Surety on this bond shall cease sixty (60) days after receipt of the termination notice by the MBP or on the filing and acceptance of a new bond whichever occurs first, except any liability or other obligation incurred before the effective date of termination.
5. This bond shall be governed by the laws of the State of Mississippi.

This bond shall become effective as of the 26th day of December, 2024.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of December, 2024.

Principal's Authorized Representative:

KalVista Pharmaceuticals, Inc.

Printed Name: _____

Signature: _____

Signed and Sealed in the presence of:

Witness: _____

Witness: _____

Surety Company's Representative:

Platte River Insurance Company

Printed Name: Steve Shike

Signature: _____

PLATTE RIVER INSURANCE COMPANY CORPORATE SEAL NEBRASKA

Signed and Sealed in the presence of:

Witness: _____

Witness: _____

PLATTE RIVER INSURANCE COMPANY
POWER OF ATTORNEY

AM3276942
Bond Number

KNOW ALL MEN BY THESE PRESENTS, That the **PLATTE RIVER INSURANCE COMPANY,** a corporation of the State of Nebraska, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

Steve Shike
Name of Individual

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

$ 100,000.00 (Bond Amount) for AM3276942 (Bond Number) on behalf of KalVista Pharmaceuticals, Inc. (Principal)

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **PLATTE RIVER INSURANCE COMPANY** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED,** that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **PLATTE RIVER INSURANCE COMPANY** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of January, 2020.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Suzanne M. Broadbent
Assistant Secretary

PLATTE RIVER INSURANCE COMPANY

John L. Sennott, Jr.
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of January, 2020 before me personally came John L. Sennott, Jr., to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is Chief Executive Officer and President of **PLATTE RIVER INSURANCE COMPANY,** the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **PLATTE RIVER INSURANCE COMPANY,** a Nebraska Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 26th day of December, 2024.

Andrew B. Diaz-Matos
Senior Vice President, General Counsel and Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

PR-ePOA (Rev. 01-2020)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler KalVista Pharmaceuticals, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 55 Cambridge Pkwy, Ste 901E

City Cambridge State MA Zip 02142

Mailing Address (if different from physical address) 55 Cambridge Pkwy, Ste 900

City Cambridge State MA Zip 02142

Telephone 857-999-0075 Website www.kalvista.com

Licensing Company Email usstatelicensing@kalvista.com

Section 2: Personal Information

First Douglas Middle Keith Last Tennison

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

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

Mailing Address 55 Cambridge Parkway, Suite 901E

City Cambridge State MA Zip [redacted]

Telephone [redacted] Email ktennison@kalvista.com

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

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

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

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

School Name		From - To (MM/YY – MM/YY)	
Lamar University		1994-1998	
Address	**City**	**State**	**Zip**
4400 S M L King Jr Pkwy	Beaumont	TX	77705
Diploma/Degree obtained, if any			
B.S. Pre-Med Biology			

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		-2004	
Address	**City**	**State**	**Zip**
4025 S Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
MBA, Specialty in Healthcare Management			

School Name		From - To (MM/YY – MM/YY)	
Silsbee High School			
Address	**City**	**State**	**Zip**
1575 US Hwy 96 N	Silsbee	TX	77656
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/15 - Present	[redacted]	Framingham	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
KalVista Pharmaceuticals, Inc.			11/23 - Present
Business Address	**City**	**State**	**Zip**
55 Cambridge Pkwy, Ste 901E	Cambridge	MA	02142
Phone	**Title**	**Number of Employed Hours**	
857-999-0075	VP, Market Access	2000	
Description of Duties			
See Attached			

Business Name			From - To (MM/YY – MM/YY)
UCB			04/21 - 11/23
Business Address	**City**	**State**	**Zip**
87 Cambridge Park Dr	Cambridge	MA	02140
Phone	**Title**	**Number of Employed Hours**	
(617) 401-4060	US Head of Market Access Strategy	5000	
Description of Duties			
See Attached			

Business Name			From - To (MM/YY – MM/YY)
Sunovion Pharmaceuticals			09/11 - 04/21
Business Address	**City**	**State**	**Zip**
84 Waterford Dr, Marlborough	Marlborough	MA	01752
Phone	**Title**	**Number of Employed Hours**	
(508) 481-6700	Multiple - See Attached	19,700	
Description of Duties			
See Attached			

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

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

Continue on next page if additional space is needed.

Douglas Keith Tennison, MBA, CHEP
[redacted]

CAREER SUMMARY

Accomplished life sciences leader with over 25 years of biopharmaceutical industry experience. Product launch expertise in multiple therapeutic areas including assets within the rare disease, specialty, drug-device and innovative distribution categories. Success in creating new access and collaborations within Payer Organizations, Integrated Delivery Networks, and Provider Groups. Corporate and Field innovator for customer-facing market access and sales functions in fast-paced launch environments focused on value, cost, and outcomes. Successful development and execution of market access strategy, operations, and key account management deployments into critical healthcare ecosystems. Competencies include leading teams with a strong focus on product launch and business unit innovation efforts.

PROFESSIONAL EXPERIENCE

Vice President, Market Access
KalVista Pharmaceuticals
November 2023- Current

- Reporting to the Chief Commercial Officer and Leading the Market Access Organization
- Responsible for the development of US Market Access sebetralstat launch strategy and go-to-market plan
- Design, build, and lead a high performing team to deliver value strategy, HEOR, payer account, patient services, specialty pharmacy, and 3PL distribution support
- Design, build, and lead patient services and patient support programs
- Champion pricing and reimbursement needs and ensure alignment between all team members
- Identify Payer unmet needs, assessing value potential, identifying access challenges and solutions, overseeing tactical plans, and supporting partner negotiations
- Oversee all aspects of contracting, vendor management, reporting, and analytics

U.S. Head of Market Access Strategy
UCB
April 2021- November 2023

- Reporting the U.S. President of UCB and leading the Market Access Strategy Organization for Epilepsy and Rare Syndromes
- Responsible for creating access via innovative collaborations within Payer, IDN, Specialty Pharmacy and Channel ecosystems
- Building the organizational approach to Alternative and Innovative Business models for post LOE, in-line, and launch assets including Authorized Generics and novel Patient Services Programs
- Leading the development of all Market Access customer-facing Value materials
- Part of the US leadership team for portfolio launch efforts, including asset due diligence and new asset integration
- Supporting the patient journey by leading patient services programs within the U.S. Neurology Portfolio
- Key collaborator for digital asset development for multichannel and stakeholder engagement
- Representing the Market Access organization for the development of real-world-evidence and pre-launch clinical value programs
- Responsible for setting the US Strategy for asset pricing, contracting, channel, distribution and specialty pharmacy
- Leading the Value Based Contracting customer facing organization
- Extensive collaborations within Brand Marketing, Sales, Health Economics and Outcomes Research, Medical, Training, Clinical Development, and Global Market Access functions

Director, Corporate Health Systems Accounts, Market Access
Sunovion Pharmaceuticals
April 2019- April 2021

- Opportunity to lead within a newly developed customer-facing role guided by the Health Systems Innovation Project
- Points of contact include Corporate C-suite executives and access decision makers within segmented integrated delivery networks, accountable care organizations, supply chains, provider groups and associated payer organizations
- Critical responsibilities for creating new access for launch assets including, contracting, and reimbursement for marketed products within national, regional, and payer/provider network customers
- Strategic leader within a team of sales and market access professionals deployed to support population health outcomes within key healthcare ecosystems across the U.S.

Director, Business Operations, Market Access
Sunovion Pharmaceuticals
August 2015-April 2019

- Committed to ensuring operational excellence within the Market Access Business Unit including cross-functional partnerships related to the commercialization and launch of multiple new therapies
- Primary responsibilities include leading as Chief of Staff to the Market Access Field organization while meeting the needs of internal and external customers through business model innovation
- Key contributions include translating strategic direction into action and serving as corporate strategy partner to multiple functions such a Market Access Marketing and Brand Leadership
- Direct customer facing team member deployed to critical market areas to establish access and optimize strategy with both Payer and Integrated Delivery Network customers
- Key partner in developing the new Health Systems Innovation Program focused on Payer/Provider joint ventures
- Directly developed Payer (corporate, public, and regional managed care organization) and Provider (integrated delivery network and accountable care organization) strategy for multiple product launches and in-process launch programs
- Leader and developer of market access value programs, payer segmentation and metrics, field deployments, CRM tools, analytics resources, contracting terms, and pricing recommendations for launch and in-line programs.

Regional Business Manager, Sales
Sunovion Pharmaceuticals
February 2013-August 2015

- Responsible for recruiting, hiring and leading a field team to support the launch of Sunovion's products in the Psychiatry market
- Consistently achieved the number one position within the Area and honored with the highest Sales award for the business unit
- Nationally honored with the first corporate field leadership rotation for pilot, license, and launch of a national digital communication platform
- Selected as part of the team supporting psychiatry product launch efforts in the United Kingdom

Therapeutic Specialist, Sales
Sunovion Pharmaceuticals
September 2011-February 2013

- Recruited to Sunovion to assist in the launch and up-staffing of the Psychiatry Sales organization
- Objectives centered around academic and key medical center accounts
- Additional emphasis placed on formulary initiatives for hospital accounts, Regional Payer channels and local thought leader development

Regional Operations Manager, Field Leader and Senior Sales Consultant
Pfizer Pharmaceuticals
December 1998-September 2011

- Beginning my career as a primary care field sales colleague I quickly moved into roles of added responsibility including Senior Sales Consultant, Regional Operations Manager, and Field Leader
- Efforts focused on Specialty and Institutional sales in the Psychiatry, Neurology and Pain markets
- Corporate development programs in coaching, leading sales teams and strategic account management
- Led additional programs in training, CRM, and product launch

Regional Office Manager
The Nature Conservancy
August 1998-December 1998

- Post undergraduate program managing operations, conservation efforts and volunteer programs.

EDUCATION AND PROFESSIONAL CERTIFICATIONS

- Bachelor of Science, Pre-Med Biology, Lamar University, Beaumont, Texas, August, 1998
- MBA, Specialty in Healthcare Management, University of Phoenix, April, 2004
- Certified by the Healthcare Financial Management Association as a Healthcare Finance Professional (CHFP)
- Certified by the Healthcare Financial Management Association as a Specialist in Managed Care (CSMC)
- Member- Healthcare Financial Management Association

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/11/2025
Date

I, Douglas Tennison, **certify that as the designated representative for**

KalVista Pharmaceuticals, Inc.,

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

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

Douglas Tennison
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2025
Date

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

Douglas Tennison
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/2025
Date

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

State of Massachusetts, ss. County of Middlesex

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

Original Signature

2/11/2025
Date

Subscribed and Sworn to before me this 11th day of February. 2025

Notary Public Signature

ANABELA C. QUELHA
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS

Last Name	First Name
Albarran	Rachael
Almeida	Sandra
Antebi	William Moise
Armstrong	William
Arnold	Philip Jay
Ataholo	Mandingo
Atkinson	Christine Nicole
Audhya	Utpaul K
Baker	Ryan P
Balcombe	Clive
Bayliss	Natasha
Bedford	Richard
Berger	Laura
Birch	Helen
Bishop	Jessica Harris
Bjerregaard	Stefanie
Boccia	Michael P
Bowman	Peter
Boyne	Sophie
Brandl	Laurice A
Brazzillo	Karen L
Broadbent	Rachael
Broholm	Anna
Buffery	Paula
Burnett	Karin
Burrows	David
Campbell	Kimberly
Catarella	Christopher M.
Cecil	Alexander
Chess	David J
Childs	Mitchell Lewis
Chiu	Connie
Cho	Hiroyasu
Chohan	Amrit
Chuang	Ya-Hsiu
Clermont	Allen C
Cooper	John
Courington	Ann
Cox	Brian
Cox	Hannah
Croadshaw	Oliver
Cutting	Kerrie L
Davie	Rebecca
Davies	Todd M
Desai	Vibha C
Desmond	Genevieve

Dunne	Dana K
Edwardson	Heather
Eisner	Carole S
Elliott	Lucy
Evans	David Michael
Flanagan	Kathryn M
Fogarty	Dolores
Forrer	Stephane
Froio	Glen
Froio	Karen
Fromont	Christophe
Gallagher	Christopher
Gaspar	Manny
Gavin	Sam
Gilday	John
Goldman	Kara Jan
Gorsuch	Stephen
Green	Jill
Greves	William
Gruskin	Daniel
Habibullah	Masooma
Hall	Barbara
Hansen	Erik J
Hao	Xinming
Harmsen	Rebecca
Harndahl	Linda
Hasmann	Thomas
Hatch	Anna M
Heckmann	Markus
Henninger	Janine
Hernandez	Helen Esther
Hill	Marza M
Hodge	Sonya Renee
Hokanson	Lon D
Hurwitz	Mark
Iverson	Matthew S
Jaiswal	Sanjeev
Jenkins	Julie B
Jones	Sally
Joseph	Angela D
Kamalioglu	Kurt
Kang	Yi-Fan
Ketchum	Monica C
Koba	Emily J
Koelling	Axel
Kouri	Kali Farhana
Krex	Brian

Kueh	Daniel
Lauinger	David Damian
Leathard	Katie
Lee	Daniel K
Lee	Ethan
Lewis	Kirsty
Lyon	Debra
Mackin	Patrick
Marella	John
Marsh	Sally
Mayes	James
McClellan	Andrew
McCullough	David
Melyan	Zare
Miah	Shahin
Miah	Suraiya
Mitchell	Emily
Mogg	Adrian
Morrell	Andrew
Morten	Rachel
Murofusi	Masanori
Murphy	Brian
Murugesan	Nivetha
Mutch	Peter
Nerone	Miriam
Newton	John Thomas
Niemeyer	Marcus
North	Carl Leslie
O'Brien	Catherine
O'Leary	Monique
O'Reilly	John
Obara	Alicja
Okino	Yoshihide
Olsen	Elliott
Owiredu-Yeboa	Samuel
Palleiko	Benjamin
Pantaleon	Carmela D
Parsonson	Peter S
Patil	Ketan
Peat	Jake
Penn	Laura
Perla	Venu
Pethen	Stephen
Pettet	Lisa A
Piekos	Brian J
Pontes Costa	Cristiano
Popplewell	Eleanor

Provencher	Cynthia Marie
Quelha	Anabela C
Read	Dan
Richards	Jennifer Ellen
Roe	Michael Bryan
Rooker	David
Rushbrooke	Louise
Schenk	Jörn Magnus
Schiano	Serena
Schreiner	Taylor James
Sharabaika	Alexis Rae
Sharman	Johannah
Shnayder	Michelle
Silva Frade	Joao Pedro
Sinclair	Collin
Smith	Michael
Smyth	Emma
Snyder	Jennifer Elizabeth
Speer	Kirstie
Starkey	Clinton
Stay	Rachel
Stokes	Jeron Ellis
Sullivan	Julie
Sweeny	Nicole
Tennison	Keith
Toomey	Ashley B
Torrey	Christopher V
Utter	Christopher
Venn	Jacob
Verma	Anshuman
Verwee	Bertrand
Vogel	Diana E
Volcy	Kathryn I
Vrhovac	Darko
Wang	Yue
Wann	Steven Edward
Wild	Annik
Williams	Pilar
Willison	Jill Christine
Yea	Chris
Yohannes	Linda J
Yoshida	Hiroshi
Yoshida	Shigeru
Youman	Britnee
Zawadzki	Gabrielle
Zhang	Ruixin
van Kooten	Sally Rosanne

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended April 30, 2023
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-36830

KalVista Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	20-0915291
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
55 Cambridge Parkway Suite 901 East Cambridge, Massachusetts	02142
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 999-0075

Securities registered pursuant to Section 12(g) of the Act

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, $0.001 par value per share	KALV	The Nasdaq Stock Market LLC

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of common stock held by non-affiliates of the registrant calculated based on the closing price of $5.07 of the registrant's common stock as reported on The NASDAQ Global Market on October 31, 2022, the last business day of the registrant's most recently completed second quarter, was $119,620,059.

The number of shares of Registrant's Common Stock outstanding as of June 28, 2023 was 34,233,643.

DOCUMENTS INCORPORATED BY REFERENCE

Information required in responses to Part III of Form 10-K is hereby incorporated by reference to portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held in 2023. The Proxy Statement will be filed by the Registrant with the Securities and Exchange Commission no later than 120 days after the end of the Registrant's fiscal year ended April 30, 2023.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report on Form 10-K. These forward-looking statements may include, but are not limited to, statements regarding our current and future nonclinical, preclinical and clinical development activities, macroeconomic conditions, including rising inflation and interest rates, labor shortages, supply chain issues, and global conflicts such as the war in Ukraine, our future results of operations and financial position, business strategy, market size, potential growth opportunities, the efficacy and safety profile of our product candidates, expected timing and results of our clinical trials, and receipt and timing of potential regulatory designations, approval and commercialization of product candidates. In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Annual Report on Form 10-K, the terms "KalVista," the "Company," "we," "us," and "our" refer to KalVista Pharmaceuticals, Inc. and, where appropriate, its consolidated subsidiaries, unless the context indicates otherwise.

Item 1. Business.

Overview

We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of small molecule protease inhibitors for diseases with significant unmet need. We apply our insights into the chemistry and biology of proteases to develop orally delivered therapeutics with high selectivity, potency and bioavailability that we believe will make them successful treatmeots for diseases. We have used these capabilities to develop novel, small molecule plasma kallikrein inhibitors targeting the disease hereditary angioedema ("HAE"). We also are conducting preclinical development on a novel, oral Factor XIIa ("Factor XIIa") inhibitor program, which we are initially advancing to provide a next generation of HAE therapeutics and which also offers the opportunity for expansion into other high unmet need indications in the future.

HAE is a rare and potentially life-threatening, genetically-driven disease that features episodes of debilitating and often painful swelling in the skin, gastrointestinal tract or airways. Although multiple therapies have been approved for the disease, we believe people living with HAE are in need of alternatives that better meet their objectives for quality of life and ease of disease control. Other than one oral therapy approved for prophylaxis, currently marketed therapies are all administered by injection, which patients find challenging despite their efficacy because they are painful, time consuming to prepare and administer, and difficult to transfer and store. As a result, many attacks are treated too late to prevent significant symptoms, and a large percentage aren't treated at all, leading to needless suffering. We anticipate that there will be strong interest in safe and effective, orally delivered treatments, and our strategy is to develop oral drug candidates for both on-demand and prophylactic use with the goal of providing patients with a complete set of oral options to treat their disease.

Our belief that our therapies could fundamentally transform the manner in which HAE is managed is based upon extensive and continuing research we conduct with patients, physicians and payers. Recently we have conducted research to further understand the process that people living with HAE follow when determining what therapy to use, how they treat their attacks and how often they do so. In our research, which we refer to as the HAE Attack Journey, we have discovered that people living with HAE carry their on-demand treatment only approximately 33% of the time and, for this reason and others, treat only about 50% of attacks. When patients do treat, we believe they tend to delay that treatment excessively for reasons including not having their treatment with them, injection-associated pain, and lack of a private area for treatment. As a result, our data indicate that a significant majority of patients experience attacks that are more severe and last longer than if they treated earlier. Patient surveys have indicated to us, in contrast, that if provided with an oral on-demand therapy, they would expect to carry it 95% of the time, would expect to treat 94% of attacks, and 93% of patients would expect to treat their attacks earlier. This is the reason we believe that an oral on-demand therapy could represent such a significant advance.

We have advanced our candidate sebetralstat into Phase 3 clinical development as a potential oral, on-demand therapy for HAE attacks. In February 2021 we announced data from a Phase 2 efficacy trial in which sebetralstat demonstrated statistically and clinically significant responses across all primary and secondary endpoints. Based upon these data, we completed an end-of-Phase 2 meeting with the United States ("U.S.") Food and Drug Administration ("FDA") in the fall of 2021 and initiated the Phase 3 KONFIDENT clinical trial in early 2022 that is intended to support submission of a New Drug Application ("NDA"). KONFIDENT is a double-blind, placebo-controlled, event-driven crossover trial in which approximately 84 patients will treat a total of three attacks: one each with 300 mg sebetralstat, 600 mg sebetralstat, and placebo, given in a randomized sequence. The study includes both adults and adolescents ages 12 and up, and allows patients to be on approved prophylactic regimens as well as on-demand only. All attack locations are eligible for treatment, including laryngeal attacks. The primary endpoint of the study is time to beginning of symptom relief assessed using the PGI-C scale. KONFIDENT is being conducted in approximately 60 sites in 20 countries. In July 2023, we announced that we reached our enrollment target of 114 patients in the study and as a result we expect data from KONFIDENT in the fourth quarter of 2023. If the trial is successful, we anticipate submitting an NDA to the FDA in the first half of 2024.

In August 2022, we initiated KONFIDENT-S, a two-year open-label extension trial assessing the long-term safety and tolerability profile of sebetralstat. In addition, this study is examining the potential use of sebetralstat as short-term prophylaxis in the setting of medical and dental procedures, where HAE attacks are known to be triggered. We also are developing an oral disintegrating tablet ("ODT") formulation of sebetralstat and have received FDA feedback on our proposed development program to support a supplemental NDA submission, which did not include a recommendation to conduct efficacy trials. We anticipate that the ODT formulation will follow the expected initial launch formulation in the U.S. and European Union ("E.U."), although it may become the initial launch formulation in other geographies.

Sebetralstat has received Fast Track and Orphan Drug designation from the FDA, and Orphan Drug designation in the E.U. A Pediatric Investigational Plan ("PIP") has also been approved by the European Medicines Agency ("EMA") for sebetralstat.

In October 2022, we announced the termination of the Phase 2 KOMPLETE study for our potential HAE prophylactic treatment KVD824, dne to elevations in liver enzymes observed in several patients during the trial. We remain uncertain as to the cause and the potential contribution of KVD824 to these elevations, but we do not anticipate further development of KVD824.

Our oral Factor XIIa inhibitor program targets an enzyme that plays a key role in HAE, as the most upstream mechanism in the biochemical pathway that initiates HAE attacks. For this reason, we believe that inhibition of Factor XIIa will block the underlying causes of HAE attacks, including the uncontrolled generation of both plasma kallikrein and bradykinin which lead to swelling and pain. Clinical studies of an injectable Factor XIIa-inhibitory antibody have demonstrated a high degree of efficacy in preventing HAE attacks, and there are no known safety implications of long-term inhibition of this enzyme. We believe that our program has the potential to be the first orally delivered Factor XIIa inhibitor to enter clinical development, initially for HAE and over time for additional indications that are supported by scientific evidence. Our internal research team has discovered multiple series of low nanomolar potency Factor XIIa inhibitors that are both selective and orally bioavailable, and we continue to progress multiple compounds in IND-enabling studies. Concurrently, we have recently presented preclinical data supporting potential development in HAE as well as diabetic macular edema ("DME") and thrombosis.

Strategy

Key elements of our strategy include:

- *Apply our deep scientific expertise in the area of serine proteases to develop novel oral therapies for indications with high unmet need.* Our core scientific team has decades of experience working on protease inhibitors and developing compounds with high potency, selectivity and bioavailability. We have assembled a team of chemists and biologists who have demonstrated the ability to design and formulate multiple drug candidate programs from a broad variety of chemical classes, as indicated by our extensive intellectual property portfolio. Our initial focus is specifically on development of oral plasma kallikrein inhibitors for HAE and Factor XIIa inhibitors for HAE and other indications; however, we believe our scientific capabilities also can be applied to other proteases to develop therapies for diseases with high unmet need.

- *Develop multiple HAE product candidates to provide a full set of therapeutic options for patients.* We intend to develop drug candidates for both on-demand and prophylactic use to provide people living with HAE with a complete set of oral options to treat their disease. Our most advanced program for HAE is sebetralstat, for which we are currently conducting the Phase 3 KONFIDENT clinical trial to evaluate the safety and efficacy of sebetralstat as a potential oral, on-demand therapy for treatment of HAE attacks. We are also in the preclinical development stage with Factor XIIa inhibitor candidates as a potential next generation of oral prophylactic treatments that may further enhance treatment options for people living with HAE.

- *Grow our capabilities internally as well as through strategic partnerships.* We intend to retain ownership and control of our pipeline programs to key milestones and in certain markets. For certain indications, such as HAE, that can be addressed by a focused organization, we intend to keep all program rights and develop internal sales and marketing capabilities to commercialize the products in major markets. For programs that address larger markets or require greater infrastructure or resources, or for markets outside the U.S. and major E.U. countries, we may seek partners that can provide those capabilities. Decisions on whether, and when, to engage in partnerships or collaborations will be based upon our evaluations of the relative risks and rewards of those collaborations at each point in the development and commercialization cycle.

Plasma Kallikrein in HAE

Plasma kallikrein is a serine protease enzyme that is a key mediator of inflammation and edema. The body modulates the downstream inflammatory effects of plasma kallikrein through a circulating inhibitor protein called C1-esterase inhibitor ("C1-INH"). Most patients with HAE have a genetic mutation that leads to C1-INH deficiency, which results in an inability to control activated plasma kallikrein in affected tissues. This excessive activation leads to inflammation, edema, and pain.

Hereditary Angioedema

Disease Overview

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people, according to published information from an HAE patient advocacy group. Excessive plasma kallikrein activation that is not sufficiently controlled by C1-INH leads to HAE attacks, which can vary with regard to the affected tissue or organ and severity. HAE attacks include episodes of intense swelling usually in the skin, gastrointestinal tract or airways. They often lead to temporary disfiguration of various body parts including the hands, feet, face, body trunk, and genitals. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by aspbyxiation. Untreated attacks can be functionally disabling and commonly take days to fully resolve.

Attacks can occur spontaneously although they often are associated with triggers such as anxiety, stress, minor trauma, surgery, or illnesses. Trauma to the oral cavity caused by dental procedures makes HAE patients particularly vulnerable to airway attacks. The frequency of HAE attacks is highly variable, with some patients having attacks several times per week and others very infrequently. Population studies have shown that the mean number of attacks per month for patients is approximately two. Although life-threatening airway swelling is rare, published research suggests at least half of HAE patients have experienced at least one such attack and airway attacks remain a major cause of mortality in HAE patients. The severity of attacks is unpredictable and not related to their underlying frequency, and even most patients on long-term propbylaxis continue to experience breakthrough attacks on some basis.

HAE is an autosomal dominant disease, meaning that a defect in only one copy of the gene leads to symptoms and that it occurs at similar rates in both males and females. The most common cause of HAE is a defect or mutation in the gene responsible for the production of C1-INH. C1-INH is a natural plasma-borne protein that is an inhibitor of multiple serine proteases in both the complement and kallikrein kinin systems. C1-INH is the predominant physiological inhibitor of plasma kallikrein, and thereby suppresses the generation of bradykinin, a potent hormone produced by plasma kallikrein, that activates its receptors on blood vessels to increase vascular leakage. Uncontrolled plasma kallikrein activity leads to the edema that is the hallmark of HAE.

While HAE most often results from the inheritance of a defective gene from a parent, it is estimated that up to 25% of cases also arise from spontaneous mutations. Patients with C1-INH-related disease are classified as Type 1 or Type 2; Type 1 is the most common form and results in low levels of circulating C1-INH and Type 2 results in production of a low function protein. An additional form of HAE, currently referred to as normal C1-INH HAE, can occur in patients with normal levels of C1-INH for a variety of reasons including mutations in genes for Factor XII, plasminogen or angiopoetin, although in most cases a specific genetic abnormality isn't found. Selective plasma kallikrein inhibitors and a bradykinin receptor antagonist are approved therapies for HAE. As such, plasma kallikrein is a clinically validated target for HAE and previous studies have demoustrated that plasma kallikrein inhibition can both treat and prevent HAE attacks. There are currently no therapies specifically approved for normal C1-INH HAE.

Current Treatments and Market Opportunities

There are a number of marketed and development stage therapeutics for HAE, both for prophylaxis as well as on-demand use. Lanadelumab (Takhzyro®) is a monoclonal antibody against plasma kallikrein indicated for prophylaxis to prevent attacks of HAE. The prescribing information recommends subcutaneous administration every two weeks, though dosing at more extended intervals may be considered in some patients. Ecallantide (Kalbitor®) is a small protein inhibitor of plasma kallikrein that is approved for treatment of acute attacks of HAE. While effective, ecallantide has been associated with cases of anaphylaxis and its labeling approval by the FDA includes a boxed warning limiting its administration to healthcare professionals with appropriate medical support to manage anaphylaxis and HAE, and requiring close monitoring of patients. Other therapies provide C1-INH replacement to control plasma kallikrein levels. Marketed C1-INH replacement therapies include Cinryze® and Haegarda® for propbylaxis, and Berinert® for treatment of acute attacks, all of which are purified from human plasma, and Ruconest® which is a recombinant product also for treatment of acute attacks. Icatibant (Firazyr®) is a synthetic peptide-based antagonist that blocks the activity of bradykinin and is indicated for treatment of acute attacks. All of these products are administered by injection, which is typically less convenient for patients and has the potential to reduce compliance. Berotralstat (ORLADEYO®) is an oral prophylactic treatment which was launched in 2021. As a result of the lifelong nature of HAE and the challenges related to taking many of the injected therapies, patient surveys consistently indicate an overwbelming desire of patients for an oral therapy. We believe that a safe and effective oral on-demand agent has the potential to transform treatment for this disease.

We believe a further future market opportunity may exist in treatment of normal C1-INH HAE. Estimates of the size of this patient population vary widely, but we believe that the nature of normal C1-INH HAE disease may make prophylaxis less attractive for these patients than a safe and rapidiy effective, oral on-demand plasma kallikrein inhibitor therapy. There are no therapies currently approved specifically for normal C1-INH HAE.

Our Portfolio of HAE Programs

Our strategy is to evaluate and develop multiple oral molecules in pursuit of best-in-class therapies for HAE patients. The first of these product candidates being evaluated in late stage clinical trials is sebetralstat. A positive Phase 2 clinical trial for sebetralstat as a potential on-demand treatment for HAE attacks was completed in February 2021, and we are currently conducting the Phase 3 KONFIDENT clinical trial.

Sebetralstat

Evidence from studies using therapies approved for the treatment of acute HAE attacks shows that earlier treatment has a powerful impact on the efficacy outcomes, and treatment guidelines strongly recommend early treatment of attacks. Despite clear evidence that early treatment markedly reduces attack severity and duration, treatment is often delayed. In one outcome study of 207 HAE attacks, attack duration was 2.75-fold shorter when treatment was administered within 1 hour of attack onset (6.1 hours versus 16.8 hours ($p<0.001$)), yet treatment was administered more than 1 hour after attack onset in nearly 60% of attacks, and for 30% of attacks treatment was administered more than five hours after attack onset. We believe this delay in administration is due to many factors including the inconvenience of preparation and administration as well as the discomfort of injectable therapies. An oral therapy has the potential to overcome these limitations and lower the barrier for treatment for patients. The combination of the rapid uptake of sebetralstat to very high blood levels and the likelihood of earlier dosing by patients, could lead to much better disease management and prevention of attacks reaching the critical stage of significant swelling and discomfort. We therefore believe that a safe, oral on-demand treatment has the potential to become a preferred alternative for patients currently using injectable treatments, including both acute and propbylactic therapies.

In February 2021 we announced data from a Phase 2 efficacy trial in which sebestralstat demonstrated statistical and clinically significant responses across all primary and secondary endpoints. KVD900-201 was a double-blind, placebo-controlled, crossover trial investigating the safety and efficacy of a single dose of 600 mg sebetralstat as an on-demand treatment for HAE attacks in patients with Type 1 or Type 2 HAE. The trial met its primary endpoint comparing the time to use of rescue treatment within 12 hours on sebetralstat versus placebo ($p=0.001$) with rates of use at 12 hours of 15.1% following treatment with sebetralstat versus 30.2% after placebo. The trial also met all secondary endpoints: reduced worsening of attacks ($p<0.0001$; PGI-S or use of rescue) and reduced time to onset of symptom relief measured using both PGI-C ($p<0.0001$) and VAS ($p<0.0001$).

Based upon these data, we completed an end-of-Phase 2 meeting with the FDA in the fall of 2021 and initiated the Phase 3 KONFIDENT clinical trial in early 2022 that is intended to support an NDA submission. KONFIDENT is a double-blind, placebo-controlled, event-driven crossover trial in which approximately 84 patients will treat a total of three attacks: one each with 300 mg sebetralstat, 600 mg sebetralstat, and placebo, given in a randomized sequence. The primary endpoint of the study is time to onset of symptom relief using the PGI-C scale. We agreed with the FDA that this is an appropriate primary endpoint for a registration-directed trial, and in the Phase 2 study, sebetralstat achieved this endpoint in a highly statistically significant manner. KONFIDENT is being conducted in approximately 60 sites in 20 countries. We have reached our target enrollment of 114 patients in the study, and expect data from KONFIDENT in the fourth quarter of 2023. If the trial is successful, we anticipate submitting an NDA in the first half of 2024.

Sebetralstat has received Fast Track and Orphan Drug designation from the FDA and has been granted Orphan Drug designation in the E.U. A PIP has also been approved by the EMA for sebetralstat.

Factor XIIa

Factor XIIa ("FXIIa") is an enzyme that plays a key role in HAE as the most upstream mediator in the biochemical pathway that initiates HAE attacks. For this reason, we believe that inhibition of Factor XIIa will block the underlying mechanism of HAE attacks, including the uncontrolled generation of both plasma kallikrein and bradykinin which cause swelling and pain. Clinical studies of an injectable Factor XIIa-inhibitory antibody have demonstrated efficacy in preventing HAE attacks, and there are no published safety concerns of long-term inhibition of this enzyme. We believe that our program has the potential to be the first orally delivered Factor XIIa inhibitor to enter clinical development, initially for HAE and over time for additional indications that are supported by scientific evidence.

Our goal is to develop an oral FXIIa inhibitor suitable for once-daily dosing and sustained suppression of kallikrein kinin system activation. Using X-ray structure-enabled drug design, we have identified multiple series of oral FXIIa inhibitors from structurally distinct discovery lineages. These series are designed to interact with different substrate pockets of the active catalytic domain of the FXIIa enzyme, thereby providing a high level of structural diversity in our portfolio of compounds.

We have presented pharmacology data for a FXIIa compound that demonstrates our ability to achieve plasma half-life consistent with once daily dosing to provide near complete inhibition of FXIIa-mediated plasma kallikrein generation and block high molecular weight kininogen cleavage that results in generation of bradykinin. We have also shown that orally administered FXIIa compounds can protect mice from angioedema. These findings that demonstrated the oral pharmacodynamic effects of a Factor XIIa inhibitor were reported at the European Academy of Allergy & Clinical Immunology in 2022. Additional studies have demonstrated that oral administration of Factor XIIa inhibitors can protect mice from arterial thrombosis induced by iron chloride, which further demonstrates target engagement. These results have been presented at the International Society of Thrombosis and Hemostasis in June 2023.

It is our expectation that this portfolio of compounds will provide multiple opportunities for the clinical development of a once-daily administered oral FXIIa inhibitor with efficacy comparable to leading injectable therapies for HAE prophylaxis. In addition, the diversity within our portfolio creates opportunities to identify oral FXIIa inhibitors that fulfill the target profile needed for the treatment of other FXIIa-mediated diseases, including thrombosis and other diseases associated with edema and inflammation.

Competition

In treating HAE, we expect to face competition from several FDA-approved therapeutics for both prophylactic and on-demand usage. These include Takhzyro®, marketed by Takeda Pharmaceuticals Company Limited ("Takeda") in the U.S. and Europe for the prevention of angioedema attacks in adults and adolescents; Firazyr, marketed by Takeda in the U.S., Europe and certain other geographic territories for the treatment of acute angioedema attacks in adult patients; Kalbitor, an injectable plasma kallikrein inhibitor marketed by Takeda for the resolution of acute attacks in adolescent and adult HAE patients; Berinert, marketed by CSL Behring for treatment of acute abdominal, facial or laryngeal attacks of HAE in adults and adolescents, and Haegarda, also marketed by CSL Behring, for prophylaxis; Ruconest, marketed by Pharming Group for the treatment of acute angioedema attacks in adult patients; and Orladeyo, an oral prophylactic treatment marketed by BioCryst Pharmaceuticals, Inc. Firazyr became available as a generic drug in 2019 and is sold by multiple companies as generic icatibant for acute usage. We are also aware of other companies that are engaged in the clinical development of potential HAE treatments, including Pharvaris GmbH, Intellia Therapeutics, Inc., BioMarin Pharmaceutical Inc., and Ionis Pharmaceuticals, Inc.

Intellectual Property

Our success substantially depends on our ability to obtain and maintain patents and other forms of intellectual property rights for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Our patent portfolio includes patents and patent applications covering plasma kallikrein inhibitors (the "plasma kallikrein portfolio"), and patent applications covering FXIIa inhibitors (the "FXIIa portfolio").

In the plasma kallikrein portfolio, as of April 30, 2023, we are the owner of, and intend to maintain, 16 U.S. patents expiring between 2034 and 2040, absent any extensions, as well as seven pending U.S. patent applications and one pending U.S. provisional application. Any patents issuing from the foregoing U.S. patent applications, or patents arising from applications claiming priority from the foregoing U.S. provisional applications, are expected to expire between 2034 and 2044, absent any adjustments or extensions. In the plasma kallikrein portfolio, as of April 30, 2023, we are the owner of, and intend to maintain, approximately 140 pending foreign applications and approximately 453 patents in foreign jurisdictions. Any issued patents, or those issuing from these foreign patent applications, are expected to expire between 2034 and 2041, absent any adjustments or extensions. In the plasma kallikrein portfolio, as of April 30, 2023, we also control and intend to maintain two pending international applications that, if issued, are expected to expire between 2042 and 2043, absent any adjustments or extensions.

Sebetralstat is an oral plasma kallikrein inhibitor, and is covered by U.S. patents, U.S. patent applications and U.S. provisional applications, and pending international applications covering composition of matter, methods of treatment, solid form and clinical formulations. The anticipated expiration dates of these patents, patents arising from those applications, or patents arising from applications claiming priority from provisional applications range from 2035 to 2044, absent any adjustments or extensions. Sebetralstat is also covered by EPO patents, European patent applications, and expected European patent applications claiming priority from U.S. provisional applications, covering composition of matter, medical use, solid form and clinical formulations. The anticipated expiration dates of these European patents, European patents arising from applications, or European patents arising from applications claiming priority from U.S. provisional applications range from 2035 to 2044 absent any extensions.

In the FXIIa portfolio, as of April 30, 2023, we are the owner of, and intend to maintain, four pending U.S. patent applications, six pending U.S. provisional applications, two pending international applications, and 34 pending foreign applications in multiple jurisdictions. Any patents issuing from the foregoing applications, or patents arising from applications claiming priority from U.S. provisional applications, in the FXIIa portfolio are expected to expire in between 2039 and 2044, absent any adjustments or extensions.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We market or intend to market our products and services under various trademarks, and have obtained or are in the process of obtaining registered trademark protection for those trademarks in the U.S. and certain countries outside the U.S. We consider these trademarks to be valuable because of their contribution to the brand identification of our current and future products and services and for protection against counterfeits.

As of April 30, 2023, we are the owner of, and intend to maintain, trademark registrations for "KALVISTA" in six foreign countries as well as all E.U. member states via an E.U. Trade Mark (a unitary right covering all twenty-seven member states of the E.U.). We also own pending trademark applications and registrations for "KALVISTA" and the K Design in the U.S. and multiple foreign countries.

We also use other forms of protection, such as copyright and trade secret protection for our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We require our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, we also require confidentiality or service agreements from third parties that receive confidential information or materials.

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act") and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Pharmaceutical products such as small molecule drugs and biological products, or biologics used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical bold, FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically take many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials mnst be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice ("GCP") an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under protocols detailing the objectives of the trial and the criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical bold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Pbase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit -risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient wben either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinlcally meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. An NDA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the NDA includes an indication for other than a rare disease or condition. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; most applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug or biologic has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission.

The FDA may also refer applications for novel drugs, as well as drugs that present difficult questions of safety or efficacy, to be reviewed hy an advisory committee—typically a panel that includes clinicians, statisticians and other experts—for review, evaluation and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions establisbed in an approved NDA, including changes in indications, product labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition — generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing, and making a product available in the U.S. for such disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan disease use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product in the approved indication. For large molecule drugs, sameness is determined based on the principal molecular structural features of a product.

During the seven-year marketing exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product can be considered clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA user fee.

Fast Track Designation and Priority Review

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs, or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act ("BPCA"), provides a six-month extension of any patent or non-patent exclusivity for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical nr clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragrapb IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the "notice letter"). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, or a decision in the patent case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Exclusivity

Upon NDA approval of a new chemical entity ("NCE") which is a drug that contains no active moiety that bas been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragrapb IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA package insert.

Patent Term Extension

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term exteusion, bowever, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time FDA determines that the applicant did not pursue approval with due diligence.

The U.S. Patent and Trademark Office (the "USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The total patent term after the extension may not exceed 14 years, and only one patent can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., pharmaceutical and biotechnology company activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services ("CMS") other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General and the Office for Civil Rights), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs, may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. In addition, the statutory exceptions and regulatory safe harbors are subject to change.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Kura Oncology, Inc.

Physical Address: 2 Seaport Lane, Suite 8A

City: Boston State: MA Zip: 02210

Mailing Address (if different from physical address): 12730 High Bluff Drive, Suite 400

City: San Diego State: CA Zip: 92130

Telephone: (617) 588-3755 Website: www.kuraoncology.com

Name of Designated Representative (DR): Kathleen Ford

Licensing Company Email: kurastatelicensing@kuraoncology.com DR Email: kford@kuraoncology.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies/ Distributors		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): _____

Corporation Name: Kura Oncology, Inc.

Mailing Address: 12730 High Bluff Drive, Suite 400

City: San Diego State: CA Zip: 92130

Telephone: (617) 588-3755 Email: kurastatelicensing@kuraoncology.com

Contact Person Name: Kathleen M. Ford

Date of SEC Registration: 11/16/2007 | SEC Registration Number: 0001422143 | Stock Exchange Symbol: KURA

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kura Oncology, Inc.
Facility Name

Kathleen Ford
Print Name of Authorized Person Submitting Application

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

11-Feb-25
Date

Board Use Only	Date Received: 3/4/25	Amount: $1000 CK 3298

KURA ONCOLOGY

Description of Operations

Kura Oncology, Inc. is a Virtual Manufacturer. Kura Oncology, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Pharmacies & Specialty Distributors by their Third-Party Logistics Provider, Cardinal Health (dba Specialty Pharmaceutical Services), who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
Kura Oncology, Inc. is using the following contract manufacturer to produce our product:

Patheon, Inc
2100 Syntex Court
Mississauga, Canada L5N 7K9
FDA Establishment Number: 3000264888

Contact Person: Melody Farkas
Contact Number: 365-822-2803

Cardinal Health Packaging Solutions
339 Mason Road
LaVergne, Tennessee 37086
FDA Establishment Number: 3008816891

Contact Person: Tim Brown
Contact Number: 615-235-1359

Patheon Inc manufactures Kura Oncology, Inc.'s product and Cardinal Health Packaging Solutions packages finished product. At no time does Patheon Inc own the product, contract with Kura Oncology, Inc.'s customers, invoice, nor sell a Kura Oncology, Inc. product. Kura Oncology, Inc.'s products are not Controlled Substances.

Labeler Code:
84696

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health acts as Kura Oncology, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Kura Oncology, Inc.'s product throughout the United States. Cardinal Health's address is:

Cardinal Health
501 Mason Rd.
LaVergne, TN 37086
Contact Name & Number: Joe Bowman, 614-757-1110

Kura Oncology, Inc. has 175 working employees on site during normal business hours.
Kura Oncology, Inc.'s hours of operation are 8:00 am – 5:00pm Monday through Friday.
Kura Oncology, Inc.'s records are stored at Cardinal Health, 501 Mason Rd LaVergne TN, 37086
Kura Oncology, Inc.'s facility square footage is 16,541.

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, August 30, 2024 8:29 AM
To: Matt Kelly <mkelly@kuraoncology.com>
Subject: [EXTERNAL]Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 30-AUG-2024
Labeler DUNS: 962490483
Labeler Name: Kura Oncology, Inc.
Labeler Code Assigned: 84696

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Company Information

Company Name: Kura Oncology, Inc.
Address: 2 Seaport Lane, Suite 8A
City, State, Zip: Boston, MA 02210
Phone: (617) 588-3755
Website: www.kuraoncology.com
E-mail: kurastatelicensing@kuraoncology.com

FEIN: 8585008800
State of Formation: Delaware
Date Incorporated: 11/16/2007
File Number: 4459063

Ownership Information

Kura Oncology, Inc is a Publicly Traded company on the NASDAQ stock exchange under the symbol KURA.

Officers

Kathleen Ford, COO
Business Address: 2 Seaport Lane, Suite 8A Boston, MA 02210
Business Phone: 617-943-4944
Email: kford@kuraoncology.com

Troy Wilson, President and CEO
Business Address: 12730 High Bluff Drive, Suite 400 San Diego, CA 92130
Business Phone: 858-500-8888
Email: troy.wilson@kuraoncology.com

Tom Doyle, SVP, Finance and Accounting
Business Address: 12730 High Bluff Drive, Suite 400 San Diego, CA 92130
Business Phone: 858-500-8831
Email: tdoyle@kuraoncology.com

Brian Powl, Chief Commercial Officer
Business Address: 12730 High Bluff Drive, Suite 400 San Diego, CA 92130
Business Phone: 858-500-8888
Email: bpowl@kuraoncology.com

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "KURA ONCOLOGY, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4459063 8300

SR# 20250170777

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

Authentication: 202721623

Date: 01-17-25

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Kura Oncology, Inc.
2 Seaport Lane, Suite 8A
Boston, MA 02210

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200112

Type: Virtual Manufacturer

Issue Date: 11/27/2024

Expiration Date: 11/27/2025

The system will be offline for updates Thursday, February 27th from 6:00pm to 6:30pm EST.

An official website of the Commonwealth of Massachusetts Here's how you know

Mass.gov Office of Health and Human Services (EOHHS) License Verification Site

Home > Lookup a License > VIR200112 - Kura Oncology, Inc.

o view a list of status definitions please view the Bureau of Health Professions Licensure License Status Definitions.

icense Information

License Type:	Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration
License Number:	VIR200112
Status:	Current
Organization Name:	Kura Oncology, Inc.
Last Issue/Renewal Date:	November 27, 2024
Expiration Date:	November 27, 2025
Address:	2 Seaport Lane, Suite 8A Boston, MA 02210

ompliance Actions/Fines

There are no public compliance actions or fines against this license/registration record.

erification of Licensure

To generate a Verification of Licensure for this license/registration record, please click the "Generate Verification of Licensure" button below.

Generate Verification of Licensure

isclaimer: The information contained in this website ("website content") is made available as a public service by the Massachusetts epartment of Public Health (the Department). The Department considers this information to constitute primary source verification. Click here or full disclaimer.

< Back to Search Page

How To Get Help:

Mass.gov Resources

eLicensing User Guide
Bureau of Health Professions Licensure
Office of Local and Regional Health
Department of Public Health
Phone:(800) 414-0168
TTY Line:(617) 973-0988

BHPL eLicensing Support Resources

Online:eLicensing Support Request Form

DO NOT provide your Social Security Number or **Date of Birth** when contacting the eLicensing Support Desk online.

Powered By JD Software ArcHealth

First Name	Last Name
Ellen	Goodman
Paul	Inglese
Rob	Crummet
Binaifer	Balsara
Mollie	Leoni
Amy	Ottaviano
Matt	Kelly
Judith	Murphy
Cayla	Samia
Fred	D'Amato
Aurelie	Chuong
Carolyn	Jin
Corey	Mathison
Patrick	Seaman
Umanga	Treanor
Mary	Pevear
Lee	Ferrande
Arlette	Holland
Brian	Ferrucci
Devon	Harman
Amber	Fisher
Zijing	Zhang
Debbie	Tschong
Tom	Kozlek
Toyin	Akinbola
Michelle	Cyr
Victor	Gehling
Rebecca	Askeland
Hunkar	Gunes Dag
Tayla	Parker Shen
Becca	Windle
Tracy	Aurigemma
Valerie	Chamberlain Santos
Katherine	Keating
Alan	Zanichkhah
Tiffany	Eldridge
Rachel	Lewis
Yang	Song
Abigail	Holland
Jaime	Houde
Ying	Tian
Jordyn	DiLorenzo
Tianle	Chen
Neil	Brahmbhatt
Bret	Wilson
Kathleen	Ford

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-37620

KURA ONCOLOGY, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	61-1547851
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
12730 High Bluff Drive, Suite 400, San Diego, CA	92130
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 500-8800

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	KURA	The Nasdaq Global Select Market

Securities registered pursuant to 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting of common equity held by non-affiliates of the registrant was approximately $776.5 million as of June 30, 2023 based on the closing price of $10.58 as reported on the Nasdaq Global Select Market on such date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of February 20, 2024 was 76,136,963 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2024 Annual Meeting of Stockholders, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2023.

Auditor Firm Id: 42 Auditor Name: Ernst & Young LLP Auditor Location: San Diego, CA USA

KURA ONCOLOGY, INC.
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PART I

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "may," "plan," "potential," "predict," "project," "targets," "likely," "will," "would," "could," "should," "continue," and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our beliefs and opinions on the relevant subject and are based upon information available to us as of the date of this Annual Report. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on information that may be limited or incomplete, our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements. The sections in this Annual Report entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this Annual Report, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our research and development activities, clinical trials and preclinical studies;
- the early stage of products under development;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, any clinical holds established by any relevant regulatory bodies and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our future product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- government regulation;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;
- our ability to obtain additional financing;
- our use of cash, cash equivalents, investments and other resources;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing;
- our ability to attract and retain key management, scientific or clinical personnel; and
- the impact of geopolitical events and actual or threatened public health epidemics and pandemics on our business and operations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this Annual Report, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report and the documents that we reference in this Annual Report, completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and we do not assume, and specifically disclaim, any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Unless the context requires otherwise, references in this Annual Report to "we," "us" and "our" refer to Kura Oncology, Inc. In addition, our use of the word "including" in this Annual Report is not intended to be exhaustive but instead is intended to mean "including, without limitation."

Risk Factor Summary

We face many risks and uncertainties, as more fully described in this section under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

- We are highly dependent on the success of our lead product candidate, ziftomenib, which is still in clinical development, and we cannot give any assurance that ziftomenib or any of our other product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- Our discovery, preclinical and clinical development is focused on the development of targeted therapeutics for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs may never lead to marketable products.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We anticipate that our current product candidates and any future product candidates may be used in combination with third-party drugs or biologics, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.
- Our product candidates may cause serious adverse events or have unacceptable side effects that could delay, limit or prevent their development.
- Failure by us or our third-party collaborators to develop, validate and obtain regulatory approval for a diagnostic testing platform could harm our drug development strategy and operational results.
- We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We are a clinical-stage company with no approved products and no historical product revenue. Consequently, we expect that our financial and operating results will vary significantly from period to period.
- We will need to obtain substantial additional capital in connection with our continuing operations. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights to our technologies or product candidates.
- We rely on third-party contractors and organizations to conduct, and/or to supply materials to conduct, our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the supply of materials and/or the completion of such clinical trials.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals in some or all planned regions, we will not be able to commercialize, or may be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

- Any product candidate for which we obtain marketing approval will be subject to extensive post-approval regulatory requirements and could be subject to post-approval restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.
- If we are unable to, or if we do not, obtain and maintain intellectual property protection for our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be impaired.
- We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.
- Patent terms may be inadequate to protect our competitive position on our product candidates for a commercially meaningful length of time.
- We may not be successful in obtaining or maintaining necessary third-party intellectual property rights for our development pipeline through acquisitions and in-licenses.
- If we are unable to maintain the confidentiality of our trade secrets or other confidential information, our business and competitive position would be harmed.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We currently have no sales personnel. If we are unable to establish effective sales capabilities or enter into agreements with third parties to sell or market our product candidates if they obtain regulatory approval, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- We are highly dependent on our Chief Executive Officer. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock.
- The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. Our pipeline consists of small molecule product candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes, and we intend to pair them with molecular or cellular diagnostics to identify those patients most likely to respond to treatment. We are conducting clinical trials of three product candidates: ziftomenib, tipifarnib and KO-2806. We also have additional programs that are at a discovery stage. We own global commercial rights to all of our programs and product candidates. We plan to advance our product candidates through a combination of internal development and strategic partnerships while maintaining significant development and commercial rights.

Ziftomenib. Our first product candidate, ziftomenib, is a potent, selective, reversible and oral small molecule inhibitor that blocks the interaction of two proteins, menin and the protein expressed by the Lysine K-specific Methyl Transferase 2A gene, or KMT2A gene (formerly referred to as the mixed-lineage leukemia 1 gene).

We received orphan drug designation for ziftomenib for the treatment of acute myeloid leukemia, or AML, from the U.S. Food and Drug Administration, or the FDA, in July 2019. We initiated our global menin-KMT2A Phase 1/2 clinical trial of ziftomenib in relapsed or refractory AML, which we call the Kura Oncology MEnin-KMT2A Trial, or KOMET-001, in September 2019. In the Phase 1a dose-escalation portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all-comer population of 30 patients with relapsed or refractory AML. A total of 53 patients were treated in the Phase 1b dose-validation and dose-expansion portions of the trial, which consisted of two randomized expansion cohorts, each comprised of nucleophosmin 1-, or NPM1-, mutant and KMT2A-rearranged AML patients. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the recommended Phase 2 dose, or RP2D.

On June 11, 2023, we presented updated clinical data from KOMET-001, including data from Phase 1b, during a late-breaking oral session at the 2023 European Hematology Association Annual Congress in Frankfurt, Germany, or EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a complete remission, or CR, with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after hematopoietic cell transplantation, or HCT, and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with isocitrate dehydrogenase, or IDH, co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an overall response rate, or ORR, of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The median duration of response, or DoR, for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M327I was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of differentiation syndrome, or DS, was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed or refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024. In May 2023, we amended the KOMET-001 protocol to include a sub-study of ziftomenib in patients with acute lymphoblastic leukemia, or ALL, and two sub-studies of ziftomenib in patients with non-NPM1-mutant and non-KMT2A-rearranged AML. We dosed the first patients in the ALL sub-study in the first quarter of 2024, and we expect to dose the first patients in non-NPM1-mutant and non-KMT2A-rearranged AML by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The first of these studies, which we call KOMET-007, is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with cytarabine and daunorubicin, or 7+3, in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. We initiated dosing of patients in KOMET-007 in the third quarter of 2023.

On January 30, 2024, we announced preliminary data from the first 20 patients in the KOMET-007 study. The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk NPM1-mutant or KMT2A-rearranged AML and 15 patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. Patients are considered "adverse risk" if they are more than 60 years old and/or have treatment-related AML and/or adverse risk cytogenics per European LeukemiaNet.

Continuous daily dosing of ziftomenib at 200 mg was well tolerated and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a CR with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-mutant AML and one patient with KMT2A-rearranged AML. The ORR among relapsed or refractory patients treated with ziftomenib and venetoclax/azacitidine was 53% (8/15). Among all patients treated with ziftomenib and venetoclax/azacitidine, 40% (6/15) received prior treatment with a menin inhibitor. The rate of CRs or CRs with partial hematologic recovery, or CRh, in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-mutant AML and 50% (2/4) in patients with KMT2A-rearranged AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-mutant AML. As of the data cutoff, 80% (16/20) of patients remained on trial, including 100% (11/11) of all NPM1-mutant patients.

The 200 mg dose of ziftomenib cleared the safety threshold for dose escalation in the relapsed or refractory venetoclax/azacitidine cohorts and enrollment at the 400 mg dose is ongoing. We anticipate determining the RP2D of ziftomenib in combination with venetoclax and azacitidine by mid-2024, upon which we plan to initiate a Phase 1b dose validation/expansion of ziftomenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutant AML (without adverse risk) or KMT2A- rearranged AML. We also have escalated to the 400 mg dose of ziftomenib in the frontline NPM1-mutant 7 + 3 cohort, and we expect to determine the RP2D of ziftomenib in combination with 7 + 3 by mid-2024.

The second ziftomenib combination study, which we call KOMET-008, is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with

fludarabine, cytarabine, granulocyte-colony stimulating factor, or G-CSF, and idarubicin, or FLAG-IDA, or low-dose cytarabine, or LDAC, in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. On February 26, 2024, we announced that we dosed the first patient in KOMET-008.

We also intend to evaluate the use of ziftomenib as a maintenance therapy in patients with NPM1-mutant or KMT2A-rearranged AML who have undergone HCT. HCT represents the only potentially curative treatment for AML, yet the most common reason for long-term failure after HCT is disease relapse. We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy following HCT. We expect to initiate the post-transplant maintenance program in the first quarter of 2024.

On December 8, 2023, we announced a clinical collaboration with The Leukemia & Lymphoma Society, or LLS, to evaluate ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia. Under the terms of the collaboration agreement, LLS will serve as the coordinating sponsor of a Phase 1 study of ziftomenib in pediatric patients with acute leukemias in North America, the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands will serve as the coordinating sponsor of the study in Europe, and Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

Tipifarnib. Our second product candidate, tipifarnib, is a potent, selective and orally bioavailable farnesyl transferase inhibitor, or FTI, that has been previously studied in more than 5,000 cancer patients and demonstrated compelling and durable anti-cancer activity in certain patients with a manageable side effect profile.

In February 2021, tipifarnib was granted Breakthrough Therapy Designation from the FDA for the treatment of patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma, or HNSCC, with variant allele frequency $\geq$ 20% after disease progression on platinum-based chemotherapy, or high VAF.

In July 2021, we announced a clinical collaboration with Novartis Pharma AG, or Novartis, to evaluate the combination of tipifarnib and alpelisib, a PI3 kinase alpha inhibitor, in patients with HNSCC whose tumors have HRAS overexpression and/or PIK3CA mutation and/or amplification. In the fourth quarter of 2021, we commenced a Phase 1/2 open-label, biomarker-defined cohort study, which we call the KURRENT-HN trial, to evaluate the safety and tolerability of the combination, determine the recommended dose and schedule for the combination, and assess early antitumor activity of the combination for the treatment of such patients. Under the terms of our collaboration agreement with Novartis, we sponsor the KURRENT-HN trial and supply tipifarnib, and Novartis supplies alpelisib. In December 2021, we announced dose administration for the first patient in the PIK3CA cohort in KURRENT-HN. In October 2022, we reported the first demonstration of a durable clinical response with the combination of tipifarnib and alpelisib in a patient with PIK3CA-mutated squamous cell carcinoma of the tonsil. Since that time, we have continued dose escalation and have observed evidence of clinical activity, along with a manageable safety profile, at multiple doses. We continue to evaluate patients in the dose-escalation study to inform the selection of the optimal biologically active dose, or OBAD, for the combination, which we expect to determine by the end of 2024. Once we determine the OBAD, we will continue to evaluate whether the activity supports the development and commercialization of the combination in HNSCC.

KO-2806. Our newest product candidate, KO-2806, is a next-generation FTI that we believe demonstrates improved potency, pharmacokinetic and physicochemical properties relative to earlier FTI drug candidates. In January 2023, we announced the clearance by the FDA of our investigational new drug, or IND, application for KO-2806 for the treatment of advanced solid tumors.

We delivered multiple presentations of preclinical data in 2023 that we believe support the development of FTIs such as KO-2806 in combination with targeted therapies.

In April 2023, we presented preclinical data at the American Association for Cancer Research Annual Meeting highlighting the potential use of FTIs in combination with two distinct classes of targeted therapies. The first of two posters revealed robust synergy between tipifarnib and the standard-of-care antiangiogenic tyrosine kinase inhibitor, or TKI, axitinib in cell- and patient-derived xenograft, or PDX, models of clear cell renal cell carcinoma, or ccRCC. The second poster reported regression of multiple models of KRAS inhibitor-resistant non-small cell lung cancer, or NSCLC, by addition of tipifarnib to adagrasib or sotorasib.

On September 28, 2023, we presented preclinical data in an oral session at the 5th RAS-Targeted Drug Development Summit supporting the development of KO-2806 in combination with $KRAS^{G12C}$ inhibitors to drive tumor regressions and durable responses in $KRAS^{G12C}$-mutant NSCLC. $KRAS^{G12C}$ inhibitors have previously been shown to activate receptor tyrosine

kinase signaling, leading to ERK-RSK and/or mTOR-S6 pathway reactivation. Our preclinical data show that co-treatment of preclinical models of $KRAS^{G12C}$-mutant NSCLC with KO-2806 and adagrasib deepens signaling inhibition at multiple nodes, including the mitogen-activated protein kinase and mTOR pathways, while decreasing cell proliferation. In both cell-derived xenograft, or CDX, and PDX models originating from NSCLC tumors, the combination of KO-2806 with adagrasib induced tumor regressions. In addition, the CDX and PDX models demonstrated enhanced duration and depth of antitumor response compared to adagrasib as a single-agent therapy.

On October 13, 2023, we presented preclinical data at the AACR-NCI-EORTC International Conference supporting the development of KO-2806 with targeted therapies, including TKIs, $KRAS^{G12C}$ inhibitors and $KRAS^{G12D}$ inhibitors. The first of three posters illustrated that KO-2806 potentiates the antitumor activity of cabozantinib in ccRCC models. The second poster illustrated that KO-2806 blocks oncogenetic signaling at multiple nodes to enhance the antitumor activity of $KRAS^{G12C}$ inhibitor adagrasib in $KRAS^{G12C}$ NSCLC. The third poster illustrated that KO-2806 constrains compensatory signaling reactivation to deepen responses to $KRAS^{G12D}$ inhibition.

We believe these data support our rationale to combine KO-2806 with TKIs in ccRCC and with $KRAS^{G12C}$ inhibitors in NSCLC.

We are evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of KO-2806 as a monotherapy and in combination with other targeted therapies in a Phase 1 first-in-human study, which we call the FIT-001 trial. On October 19, 2023, we announced that we dosed the first patient in the monotherapy portion of the FIT-001 trial. We anticipate dosing the first patients with KO-2806 in combination with cabozantinib in ccRCC by mid-2024. On November 2, 2023, we announced a clinical collaboration with Mirati Therapeutics, Inc., or Mirati, to evaluate the combination of KO-2806 and adagrasib in patients with NSCLC whose tumors have a $KRAS^{G12C}$ mutation. Under the terms of the agreement, Mirati will supply us with adagrasib for the NSCLC combination cohort of the FIT-001 trial, and we sponsor the trial. We anticipate initiation of the $KRAS^{G12C}$-mutant NSCLC cohort by mid-2024.

Our Strategy

Our strategy is to discover, acquire, develop and commercialize innovative anti-cancer agents in oncology indications with significant unmet medical need and attractive commercial potential. The key components of our strategy include the following:

- Focus on developing novel, small molecule product candidates for the treatment of cancer;
- Identify molecular, genetic or other tumor-related characteristics of patients more likely to benefit from our product candidates;
- Leverage clinical and pathology trends towards comprehensive tumor profiling and the use of companion diagnostics;
- Pursue opportunities to enhance clinical activity, minimize toxicity and address innate and adaptive resistance to standard of care therapies through rational combinations;
- Build a sustainable product pipeline and advance our programs through a combination of internal discovery and development and external sources, including strategic partnerships, collaborations, in-licenses and acquisitions;
- Maintain significant development and commercial rights to our product candidates; and
- Invest in pre-commercial activities to maximize the value of our pipeline assets.

Precision Medicines in Cancer Treatment

Advancements in cancer genetics and new molecular diagnostic tools are helping define why some patients respond to a specific therapy while other patients receive little to no clinical benefit. This area of cancer drug discovery and development offers the potential for innovative treatments that are safer and more effective for patients with specific cancers. We aim to improve patient outcomes and contribute to the reduction in healthcare costs by matching targeted therapeutics to the patients who will derive the most benefit. We are developing a pipeline of small molecule product candidates designed to inhibit mutated or abnormally functioning cellular pathways that drive cancer growth or drug resistance and intend to pair them with molecular diagnostics to identify those patients with tumors most likely to respond to treatment. This approach to treatment is known as precision medicine.

A pioneering example of a precision medicine in cancer was the development of small molecule inhibitors against EGFR in patients with advanced lung cancer. Patients with EGFR mutations treated with EGFR inhibitors have a response rate in the 65% range, as opposed to a response rate of approximately 10% in unselected lung patients. Erlotinib (Tarceva®) was approved in the United States as a first-line treatment for patients with NSCLC characterized by EGFR mutations. Other examples of approved agents developed using precision medicine approaches include ALK, BCR-ABL, BRAF, ROS1, RET and TRK inhibitors.

Precision medicine has several advantages over traditional drug development. We believe evidence-based selection of patients who are more likely to respond to a targeted therapy based on tumor biology provides the potential for: higher translatability from preclinical to clinical studies; increased overall response rates, requiring fewer enrolled patients for clinical development; expedited clinical development in areas of high unmet need and improved safety relative to standard chemotherapy. We believe the precision medicine approach has the potential for more efficient drug development with reduced risks, costs and timelines. However, achieving success through a precision medicine approach is predicated on a thorough understanding of tumor biology and the mechanism of action of the product candidate. To develop this understanding, we have conducted extensive translational research on each of our programs.

Our Approach to Development of Precision Medicines in Oncology

Translational research is the practice of synthesizing our knowledge of basic research, preclinical and clinical data to develop a "bench-to-bedside" understanding of the potential of our product candidates, and it is the principal methodology we utilize to guide our precision medicine approach. We evaluate our product candidates through both *in vitro* and *in vivo* experiments to evaluate their potential as therapeutics using a number of tools, including PDX models. PDX models mostly retain the principal histologic and genetic characteristics of their donor tumor and have been shown in many instances to be predictive of clinical outcomes and are increasingly being used for preclinical drug evaluation, biomarker identification, biologic studies and personalized medicine strategies. We evaluate our product candidates in preclinical PDX studies seeking to corroborate clinical data and to identify and prioritize potential clinical indications.

Because we often target molecular and/or genetic alterations that are detectable, companion diagnostic tests can be developed to identify these alterations. Once we have identified a target, we will initially use existing diagnostic tools, such as molecular assays (next-generation sequencing, or NGS, and/or qualitative polymerase chain reaction of DNA and/or RNA), or tissue-based assays such as protein expression by immunohistochemistry to identify patient subsets that we believe will derive increased benefit from our product candidates. As we advance our product candidates clinically and determine the most important screening criteria, we intend to develop companion diagnostics as appropriate, with the help of technology partners, to seek to identify patients, and if our clinical development programs are successful, to support the potential registration and marketing of our product candidates.

Our clinical development strategy employs a disciplined approach designed to identify response signals early in development and reduce development risks. Based upon the data from our preclinical studies as well as clinical data, we seek to evaluate our product candidates in well-defined patient populations and believe this gives us a higher likelihood of demonstrating a clinical benefit. This approach is intended to allow for early insight into the therapeutic potential of a product candidate and the possibility for rapid clinical development and expedited regulatory strategies.

We are employing some or all of the steps above across our various programs as we advance our pipeline of targeted therapies. We believe the advantages of such an approach are the potential for higher translatability from preclinical to clinical studies, the ability to leverage clinical and pathology trends towards comprehensive tumor profiling and the potential for expedited clinical development.

Clinical Programs and Pipeline

Ziftomenib – A Selective Inhibitor of the Menin-KMT2A Interaction

Overview

We are developing ziftomenib, an orally bioavailable small molecule inhibitor of the menin-KMT2A interaction, for the treatment of genetically defined subsets of acute leukemias, including AML and ALL. The menin-KMT2A program was licensed from the Regents of the University of Michigan, or the University of Michigan.

Acute Leukemias and Genetic Alterations

Acute leukemias, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as NPM1, are characterized by chromosomal translocations of the KMT2A gene that are primarily found in patients with AML and ALL and affect both children and adults. These translocations form oncogenes encoding KMT2A fusion proteins, which play a causative role in the onset, development and progression of KMT2A-rearranged leukemias. KMT2A fusion proteins drive the upregulation of expression of a small set of target genes involved in the malignant transformation of blood cells, however, the fusion protein is critically dependent on binding the oncogenic co-factor menin to function. This implies that the menin-KMT2A interaction represents a valuable target for molecular therapy and supports the development of inhibitors of the menin-KMT2A protein-protein interaction.

The target genes of the KMT2A fusion proteins are also found to be overexpressed in a broader subset of AMLs characterized by mutations in NPM1, DNMT3A, IDH1, IDH2 and a different mutation in the KMT2A gene, known as an KMT2A-partial tandem duplication. These mutations also appear to be dependent on the interaction between menin and KMT2A, suggesting that the menin-KMT2A complex is a central node in epigenetic dysregulation driven by distinct oncogenic driver mutations known to be important in AML and other hematologic malignancies.

NPM1-mutations are among the most common genetic alterations, representing approximately 30% of AML. NPM1 mutations drive leukemogenesis in AML via cytoplasmic dislocation of NPM1 protein, resulting in transcription of disease-associated genes and inhibition of normal differentiation programs. NPM1-mutant AML is highly sensitive to disruption of the menin-KMT2A complex, which leads to decreased expression of essential leukemic genes, reduction of leukemic self-renewal capacity and promotion of differentiation. While patients with NPM1-mutant AML have high response rates to frontline therapy, relapse rates are high and survival outcomes are poor. Median overall survival is only six months following relapse for NPM1-mutant patients.

KMT2A-rearrangements represent approximately 5-10% of AML. Patients with KMT2A-rearranged AML have a poor prognosis with high rates of resistance and relapse following standard of care therapies. Currently, there are no approved therapies indicated for NPM1-mutant or KMT2A-rearranged leukemias. In the pediatric population, KMT2A-rearranged leukemias make up approximately 10% of acute leukemias. In the case of infant leukemias, the frequency of KMT2A rearrangements is 70–80%. These pediatric leukemia sub-types portend a poorer prognosis and five-year survival rate that is lower than other leukemia sub-types and therefore represent a significant unmet medical need given the lack of curative therapeutic options.

In adults, AML is the most common acute leukemia worldwide. Despite the many available treatments for AML, prognosis for patients remains poor. Approximately 50% of patients with AML who achieve a CR after induction therapy relapse, and 40% of patients relapse after undergoing HCT. By preventing the interaction of menin and KMT2A/MLL, we believe ziftomenib has the potential to address up to 50% of AML cases, including NPM1-mutant AML and KMT2A-rearranged AML.

Preclinical Data Supporting Ziftomenib as a Monotherapy and in Combination with Other Therapies

We have generated preclinical data that support the potential anti-tumor activity of ziftomenib in genetically defined subsets of acute leukemia, including those with rearrangements or partial tandem duplications in the KMT2A gene as well as those with oncogenic driver mutations in genes such as NPM1. Our preclinical data support the hypothesis that ziftomenib targets epigenetic dysregulation and removes a key block to cellular differentiation to drive anti-tumor activity.

In November 2017, we reported preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing robust and durable activity in multiple *in vivo* models of AML characterized by KMT2A-rearrangements or mutations in NPM1, DNMT3A, IDH1 and IDH2. We have further demonstrated that the inhibition of the menin-KMT2A interaction results in the down-regulation of KMT2A fusion target genes and an upregulation of markers of differentiation.

In December 2021, we reported the presentation of preclinical data for ziftomenib and its potential for synergistic activity in combination with the BCL2 inhibitor venetoclax, a current standard of care in the treatment of patients with AML. These data confirm that treatment with ziftomenib drives dose-dependent induction of growth inhibition, differentiation and loss of viability of AML cells with KMT2A rearrangements or NPM1 mutations, while also reducing key protein levels such as MEIS1, FLT3 and BCL2 and menin itself. In addition, the findings demonstrated that co-treatment with ziftomenib and venetoclax induces synergistic activity in patient-derived AML cells expressing KMT2A rearrangements or NPM1 mutations, with or without mutant FLT3 expression, and prolongs survival in an aggressive disseminated model of KMT2A-rearranged, FLT3-mutant AML.

Clinical Development of Ziftomenib in AML

In September 2019, we initiated the KOMET-001 trial, a Phase 1/2 clinical trial of ziftomenib in patients with relapsed or refractory AML to investigate the safety and tolerability of ziftomenib in humans, determine a RP2D, characterize pharmacokinetics of ziftomenib and assess any early evidence of clinical activity.

In December 2020, we announced preliminary results from our KOMET-001 trial at an oral presentation at the 2020 American Society of Hematology Annual Meeting, or ASH. As of the data cutoff date for the ASH presentation, November 2, 2020, the trial had enrolled 12 patients with relapsed or refractory AML, of whom ten were evaluable for safety and tolerability and eight were evaluable for efficacy. Clinical or biological activity was reported in six of the eight efficacy-evaluable patients, including two patients achieving a CR, one patient achieving a morphological leukemia-free state, and one patient experiencing a marked decrease in hydroxyurea requirements and having attained peripheral blood count stabilization. As presented at ASH, ziftomenib was well tolerated with a manageable safety profile. As of the data cutoff date, no drug discontinuations due to treatment-related adverse events and no evidence of QTc prolongation were reported. Treatment related adverse effects (grade $\geq$ 3) were reported to include pancreatitis, increased lipase, decreased neutrophil count, tumor lysis syndrome and deep venous thrombosis.

In May 2021, we reported that we amended the KOMET-001 trial protocol to include two Phase 1b expansion cohorts at doses that cleared the safety threshold in dose escalation. The Phase 1b portion of the study was designed to determine the lowest dose of ziftomenib that provides maximum biologic and clinical effect, consistent with guidance from the FDA relating to targeted oncology therapies, known as Project Optimus.

In June 2021, we reported that we dosed our first patient in the Phase 1b expansion cohorts. Each cohort – a lower dose (200 mg) and a higher dose (600 mg) – was comprised of NPM1-mutant and KMT2A-rearranged relapsed or refractory AML patients. Both doses demonstrated preliminary evidence of activity and safety and were determined to be well tolerated in the Phase 1a portion of the study.

In November 2021, we reported that the FDA had placed the KOMET-001 trial on a partial clinical hold. The partial clinical hold was initiated following our report to the FDA of a Grade 5 serious adverse event potentially associated with DS, a known adverse event related to differentiating agents in the treatment of AML. Patients who were enrolled in the Phase 1b expansion cohort at the time of the partial clinical hold were permitted to continue to receive ziftomenib, although no additional patients were to be enrolled until the partial clinical hold was lifted. In January 2022, we announced that the FDA had lifted the partial clinical hold on the KOMET-001 trial following agreement on our mitigation strategy for DS, and that the study would resume screening and enrollment of new patients.

In August 2022, we announced that we completed enrollment in the Phase 1b expansion cohorts of the KOMET-001 trial.

In December 2022, we announced updated clinical data from Phase 1a of the KOMET-001 trial that were presented during an oral presentation session at ASH. In the Phase 1a portion of the KOMET-001 trial, ziftomenib demonstrated a wide therapeutic window and encouraging monotherapy activity in an all comer population of 30 patients with relapsed or refractory AML.

On June 11, 2023, we presented updated clinical data from KOMET-001, including data from Phase 1b, during a late-breaking oral session at EHA, including durable activity in patients with heavily pretreated and co-mutated relapsed or refractory NPM1-mutant AML. A total of 53 patients were treated in the Phase 1b dose-validation and dose-expansion portions of the study. Ziftomenib demonstrated optimal clinical benefit at 600 mg in the Phase 1b portion of the KOMET-001 trial and this dose was designated as the RP2D.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with NPM1-mutant AML treated at the RP2D of 600 mg achieved a CR with full count recovery. An eighth patient, who had a CR with partial count recovery after treatment with ziftomenib, subsequently evolved to a CR with full count recovery after HCT and remained on study as of the date of the EHA presentation. In addition, a patient with NPM1-mutant AML treated at 200 mg remained on ziftomenib for 36 cycles as of the data cutoff.

Durable remissions were observed in patients with NPM1 mutations and other key co-mutations following treatment with ziftomenib. Notably, 33% (2/6) of patients with FLT3 co-mutations, 50% (4/8) of patients with IDH co-mutations and 50% (2/4) of patients with both FLT3 and IDH co-mutations achieved a CR at the 600 mg dose of ziftomenib. Ziftomenib demonstrated an ORR of 45% in patients with NPM1-mutant AML treated at the 600 mg dose. The median DoR for all NPM1-mutant patients treated at 200 mg or 600 mg in the Phase 1a/b portion of the study was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median DoR for such patients censored at stem cell transplant was 5.6 months (95% CI: 1.0 to NE).

As part of an ongoing analysis, the resistance mutation MEN1-M327I was detected in three patients treated with ziftomenib: in two of these three patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations occur at a low frequency even after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains binding affinity against the MEN1-T349M mutation, which was detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the reported adverse event profile remained consistent with features of underlying disease. The on-target effect of DS was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

On February 9, 2023, we announced the dosing of the first patients in the Phase 2 registration-directed portion of the KOMET-001 study of ziftomenib in patients with relapsed or refractory NPM1-mutant AML. Enrollment in the Phase 2 study continues to outperform our projections. The study is expected to enroll a total of 85 patients at approximately 60 U.S. and European sites. We anticipate completion of enrollment of all 85 patients by mid-2024. In May 2023, we amended the KOMET-001 protocol to include a sub-study of ziftomenib in patients with ALL, and two sub-studies of ziftomenib in patients with non-NPM1-mutant and non-KMT2A-rearranged AML. We dosed the first patients in the ALL sub-study in the first quarter of 2024, and we expect to dose the first patients in non-NPM1-mutant and non-KMT2A-rearranged AML by mid-2024.

In addition to our monotherapy study of ziftomenib, we have initiated a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The first of these studies, which we call KOMET-007, is designed to evaluate ziftomenib in combination with venetoclax and azacitidine in patients with newly diagnosed or relapsed or refractory NPM1-mutant or KMT2A-rearranged AML, and ziftomenib in combination with 7+3 in patients with newly diagnosed NPM1-mutant or KMT2A-rearranged AML. We initiated dosing of patients in KOMET-007 in the third quarter of 2023.

On January 30, 2024, we announced preliminary data from the first 20 patients in the KOMET-007 study. The first 20 patients were enrolled in KOMET-007 between July 2023 and November 2023, including five newly diagnosed patients with adverse risk NPM1-mutant or KMT2A-rearranged AML and 15 patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. Patients are considered "adverse risk" if they are more than 60 years old and/or have treatment-related AML and/or adverse risk cytogenics per European LeukemiaNet.

Continuous daily dosing of ziftomenib at 200 mg was well tolerated and the safety profile was consistent with features of underlying disease and backbone therapies. No differentiation syndrome events of any grade were reported, and no dose-limiting toxicities, evidence of QTc prolongation, drug-drug interactions or additive myelosuppression were observed. As of the data cutoff on January 11, 2024, all newly diagnosed patients treated with ziftomenib and 7+3 achieved a CR with full count recovery, for a CR rate of 100% (5/5), including four patients with NPM1-mutant AML and one patient with KMT2A-rearranged AML. The ORR among relapsed or refractory patients treated with ziftomenib and venetoclax/azacitidine was 53% (8/15). Among all patients treated with ziftomenib and venetoclax/azacitidine, 40% (6/15) received prior treatment with a menin inhibitor. The rate of CRs or CRhs in patients who were menin inhibitor naïve was 56% (5/9), including 60% (3/5) in patients with NPM1-mutant AML and 50% (2/4) in patients with KMT2A-rearranged AML. The ORR in patients who received prior venetoclax was 40% (4/10), including 60% (3/5) in patients with NPM1-mutant AML. As of the data cutoff, 80% (16/20) of patients remained on trial, including 100% (11/11) of all NPM1-mutant patients.

The 200 mg dose of ziftomenib cleared the safety threshold for dose escalation in the relapsed or refractory venetoclax/azacitidine cohorts and enrollment at the 400 mg dose is ongoing. We anticipate determining the RP2D of ziftomenib in combination with venetoclax and azacitidine by mid-2024, upon which we plan to initiate a Phase 1b dose validation/expansion of ziftomenib in combination with venetoclax and azacitidine in newly diagnosed patients with NPM1-mutant AML (without adverse risk) or KMT2A- rearranged AML. We also have escalated to the 400 mg dose of ziftomenib in the frontline NPM1-mutant 7 + 3 cohort, and we expect to determine the RP2D of ziftomenib in combination with 7 + 3 by mid-2024.

The second ziftomenib combination study, which we call KOMET-008, is designed to evaluate ziftomenib in combination with gilteritinib in patients with relapsed or refractory NPM1-mutant AML, and ziftomenib in combination with FLAG-IDA or LDAC in patients with relapsed or refractory NPM1-mutant or KMT2A-rearranged AML. On February 26, 2024, we announced that we dosed the first patient in KOMET-008.

Registration Strategy for Ziftomenib. Our immediate strategy for ziftomenib in AML is to generate a data package to support an application for marketing approval in relapsed or refractory NPM1-mutant AML. Our comprehensive clinical development plan for ziftomenib also includes the evaluation of ziftomenib in combination with standards of care for NPM1-mutant and KMT2A-rearranged AML in the frontline and relapsed or refractory settings, as described above. We also are evaluating ziftomenib in other indications, beginning with ALL, and plan to evaluate ziftomenib as a maintenance therapy.

We are supporting an investigator-sponsored study, and plan to initiate a company-sponsored study, evaluating the ability of ziftomenib to improve outcomes when administered as a maintenance therapy to patients with NPM1-mutant or KMT2A-rearranged AML following HCT.

Our clinical development plan also includes a pediatric development strategy. On December 8, 2023, we announced a clinical collaboration with LLS to evaluate ziftomenib in combination with chemotherapy in pediatric patients with relapsed or refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia. Under the terms of the collaboration agreement, LLS will serve as the coordinating sponsor of a Phase 1 study of ziftomenib in pediatric patients with acute leukemias in North America, the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands will serve as the coordinating sponsor of the study in Europe, and Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

Finally, several investigator-sponsored clinical trials of ziftomenib are either open for enrollment or in development, in addition to the clinical trials described above.

Farnesyl Transferase Inhibitors

Protein Farnesylation

Certain cellular proteins must associate with the intracellular membrane to function. One of the mechanisms by which proteins are associated with the inner cell membrane is farnesylation, which modifies the protein by attaching a farnesyl group. Another, related mechanism of attachment of proteins to the membrane is protein geranylgeranylation, which is attachment of a geranylgeranyl group to the protein. Protein farnesylation and protein geranylgeranylation, collectively called protein prenylation, cause intracellular proteins to become anchored to the inside of the cell membrane due to the hydrophobic nature of the farnesyl and geranylgeranyl groups.

The enzyme that catalyzes the attachment of the farnesyl groups to proteins is called farnesyl transferase. Small molecule inhibitors of the farnesyl transferase enzyme have been discovered, and several inhibitors including tipifarnib have been evaluated in human clinical trials. The small molecule inhibitors are commonly referred to as FTIs. Many proteins involved in cellular signaling undergo prenylation because they must be associated with other proteins at the inner cellular membrane of the tumor cell to function properly. Treatment of tumors with FTIs results in the reversal of several hallmarks of cancer, including mitotic arrest, induction of apoptosis, growth inhibition, tissue invasion, sustained angiogenesis and tumor growth, as well as induction of tumor regression in animal models.

Among the hundreds of proteins estimated to be prenylated, some are either exclusively farnesylated or exclusively geranylgeranylated; some are both farnesylated and geranylgeranylated, and others are naturally farnesylated but become geranylgeranylated, when the farnesyl transferase enzyme is inhibited. HRAS is an example of a protein that is exclusively farnesylated while KRAS and NRAS are two proteins that are naturally farnesylated but may become geranylgeranylated upon treatment with FTIs.

Solid Tumors with HRAS Mutations

Rat sarcoma virus, or RAS, oncogenes are translated into a family of membrane-associated proteins that are involved in regulating cell division in response to growth factor stimulation. The RAS gene family is comprised of three oncogenes: HRAS, KRAS and NRAS. Collectively, the three RAS genes constitute one of the most frequently mutated families of oncogenes in human cancers. Although HRAS mutations are less common overall relative to KRAS and NRAS mutations, they have a higher prevalence in cancers of the thyroid and urinary bladder and in head and neck squamous cell carcinomas.

The HRAS protein is involved in regulating cell division in response to growth factor stimulation. Growth factors act by binding cell surface receptors that span the cell's plasma membrane. Once activated, receptors stimulate signal transduction events in the cytoplasm, a process by which proteins and second messengers relay signals from outside the cell to the cell nucleus and instruct the cell to grow or divide. HRAS is localized in the plasma membrane, and it is an early player in many signal transduction pathways. HRAS acts as a molecular on/off switch – once HRAS is turned "on" it recruits and activates proteins necessary for the propagation of the receptor's signal. In certain solid tumors, mutations in HRAS or its upstream regulators cause HRAS to be permanently "on," resulting in persistent activation of downstream growth and proliferation signals that drive tumor cell growth. FTIs work to prevent the aberrant growth and proliferation of cells that are dependent on these signaling pathways by inhibiting protein farnesylation and subsequent membrane localization of HRAS, thereby switching HRAS "off." HRAS membrane localization is solely dependent on protein farnesylation, and therefore we believe that our FTI product candidates have the potential for the treatment of HRAS mutant solid tumors.

HNSCC is one of a number of different types of cancer that arises from squamous cells. Squamous cells are found in the outer layer of skin and in the mucous membranes, which are the moist tissues that line body cavities such as the airways and intestines. HNSCC develops in the mucous membranes of the mouth, nose, and throat and is classified by its location. HNSCC is caused by a variety of factors that can alter the DNA in cells. The strongest risk factors for developing this form of cancer are tobacco use, including smoking or using chewing tobacco, and heavy alcohol consumption. In addition, infection with certain strains of human papillomavirus is linked to the development of HNSCC.

HNSCC is a disease of high unmet need. Response rates for the three approved second-line agents, cetuximab (Erbitux®), nivolumab (Opdivo®) and pembrolizumab (Keytruda®), are in the range of 13-16% in unselected populations, with a median progression-free survival of approximately two months and a median overall survival of less than eight months. Data in the literature along with our own clinical data suggest response rates to these second-line agents in patients with HRAS mutations may be even lower.

Other types of cancer that can result from squamous cells include vulvar, penile, cutaneous and lung squamous cell carcinoma. Our preclinical and clinical data suggest that, among solid tumors with HRAS mutations, squamous cell tumors are sensitive tumors to treatment with tipifarnib, and treatment with tipifarnib can, in some patients, produce durable responses.

Tipifarnib – An Oral Farnesyl Transferase Inhibitor

Overview

Tipifarnib is a potent, selective and orally bioavailable FTI. We in-licensed tipifarnib from Janssen Pharmaceutica NV, or Janssen, an affiliate of Johnson & Johnson, in December 2014. Previously, tipifarnib was studied in more than 5,000 oncology patients in more than 70 clinical trials and was observed to be generally well tolerated with a manageable side effect

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	See Attachment A * If making a change, provide current license number: WH 02864	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Revance Therapeutics, Inc.

Physical Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: (615) 724-7755 Website: www.revance.com

Name of Designated Representative (DR): Marc Korenberg

Licensing Company Email: mkorenberg@revance.com DR Email: mkorenberg@revance.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✔	

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

A State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Crown Laboratories, Inc.

Corporation/Organization Name: Revance Therapeutics, Inc.

Mailing Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Telephone: (615) 724-7755 Email: mkorenberg@revance.com

Contact Person Name: Marc Korenberg

Section 6: Partnership

A Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

A Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification N/A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment C 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment D		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment A	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by a corporation.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment J	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Revance Therapeutics, Inc.

Facility Name

Marc Korenberg

Print Name of Authorized Person Submitting Application

Marc Korenberg

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

10/29/24

Date

Board Use Only	Date Received: 11/4/24	Amount: $1000-EC ✓

Attachment

Regarding the Ownership Change

On December 2, 2024, it is anticipated that Crown Laboratories, Inc. "Crown" will acquire Revance Therapeutics, Inc. "Revance" in a stock acquisition pursuant to an Agreement and Plan of Merger. At closing, Revance will continue as the surviving corporation and become a wholly owned subsidiary of Crown. As such, Revance will no longer be a publicly traded company. As a result, Revance's corporate officers will change. Provided below is the new corporate officer. Legal documentation effectuating the ownership change may be provided when available and upon request.

Corporate Officer:

Jeffery A. Bedard
CEO

Attachment B

Nature of Business

Revance Therapeutics, Inc. (Revance) is a manufacturer of prescription drug and distributor of a device product. Revance's Nashville, TN location sells its product, but does not physically manufacture or handle product at its business office. Revance's Newark, CA facility produces its drug product and a contract manufacturer is used to manufacture its device product. A third party logistics provider is used to ship all product. Provided below is the contact information for the manufacturing locations and third party logistics provider.

Third Party Logistics Provider:

Kuehne + Nagel, Inc.
6005 Freeport Ave., Building J
Memphis, TN 38141

Manufacturing Locations:

Prescription Drug:

Revance Therapeutics, Inc.
7555 Gateway Boulevard
Newark, CA 94560

Device:

Teoxane SA
Rue de Lyon 105, CH-1203
Geneva, Switzerland
FDA Registration #: 3005975625

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov Menu

Home Drug Databases NDC Search Result

Share Tweet LinkedIn Email Print

Current through September 26, 2024

You have searched Finished drug products

Search Results: *'Revance'*

Back to Search Page

RESET

Showing 1 to 4 of 4 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
DAXXIFY	72960-112-01	100U/1.2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAMUSCULAR	BLA761127	Revance Therapeutics, Inc.	72960-112	botulinum toxin type A	BOTULINUM TOXIN TYPE A	HUMAN PRESCRIPTION DRUG	09/20/2022	N/A	BLA
DAXXIFY	72960-112-02	100U/1.2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAMUSCULAR	BLA761127	Revance Therapeutics, Inc.	72960-112	botulinum toxin type A	BOTULINUM TOXIN TYPE A	HUMAN PRESCRIPTION DRUG	09/20/2022	N/A	BLA
DAXXIFY	72960-112-05	100U/1.2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAMUSCULAR	BLA761127	Revance Therapeutics, Inc.	72960-112	botulinum toxin type A	BOTULINUM TOXIN TYPE A	HUMAN PRESCRIPTION DRUG	09/20/2022	N/A	BLA
DAXXIFY	72960-112-06	100U/1.2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAMUSCULAR	BLA761127	Revance Therapeutics, Inc.	72960-112	botulinum toxin type A	BOTULINUM TOXIN TYPE A	HUMAN PRESCRIPTION DRUG	09/20/2022	N/A	BLA

Previous 1 Next

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Verified 11/12/24

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "REVANCE THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3074007 8300

SR# 20242166376

Authentication: 203484212

Date: 05-15-24

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

Attachment H

Resident State License

According to Tennessee law*, the anticipated change does not constitute a change in ownership. As such, a new resident state license will not be issued. Enclosed is a copy of the current resident state license.

*Tennessee Rule 1140-01-.08 (2)(b) Transactions which do not constitute a change of ownership include, but are not limited to, the following: 1. Changes in the membership of a corporate board of directors or board of trustees; 2. **Two (2) or more corporations merge and the originally licensed corporation survives;** and 3. Corporate stock transfers or sales, even when a controlling interest.

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000006844
EXPIRATION DATE: 07/31/2025

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
MANUFACTURER
REVANCE THERAPEUTICS, INC

COMMISSIONER OF HEALTH

REVANCE THERAPEUTICS, INC.
1222 DEMONBREUN STREET
SUITE 2000
NASHVILLE TN 37203

13529923
33567

State of Tennessee
Department of Health

BOARD OF PHARMACY
MANUFACTURER
REVANCE THERAPEUTICS, INC
1222 DEMONBREUN STREET
SUITE 2000
NASHVILLE TN 37203

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006844
EXPIRATION DATE: 07/31/2025

Jennifer L. Rotnaney Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

Last Updated: 3/20/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 3

Click here to return to the search page

1

REVANCE THERAPEUTICS, INC. Cardinal
Health Specialty Pharmaceutical Services 501 Mason Rd
Suite 20
La Vergne, TN 37086
Attn: Savitha Venkatesh
510-742-1000

Rank: Wholesale/Distributor
3PL Address:
6005 Freeport Ave Bldg J
Memphis, TN 38141

Facility License Number: 00005953
Status: Licensed
Date of Original Licensure: 02/19/2020
Date of Expiration: 02/28/2026
No Disciplinary Actions

2

REVANCE THERAPEUTICS, INC. Cardinal
Health Specialty Pharmaceutical Services 501 Mason Rd
Suite 20
La Vergne, TN 37086
Attn: Savitha Venkatesh
510-742-1000

Rank: Manufacturer
3PL Address:
6005 Freeport Ave Bldg J
Memphis, TN 38141

Facility License Number: 00005954
Status: Licensed
Date of Original Licensure: 02/19/2020
Date of Expiration: 02/28/2026
No Disciplinary Actions

3

Revance Therapeutics, Inc
1222 Demonbreun Street Suite 2000
Nashville, TN 37203
615-724-7755

Rank: Manufacturer
3PL Address:
6005 Freeport Ave Bldg 1
Memphis, TN 38141

Facility License Number: 00006844
Status: Licensed
Date of Original Licensure: 07/21/2021
Date of Expiration: 07/31/2025
No Disciplinary Actions

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/10/2024

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

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

PRODUCER
Marsh & McLennan Agency LLC
Marsh & McLennan Ins Agency LLC
1255 Treat Boulevard #950
Walnut Creek CA 94597

License#: 0H18131

CONTACT NAME: Felicia McAroy
PHONE (A/C, No, Ext): 925-482-9337 **FAX (A/C, No):** 925-482-9390
E-MAIL ADDRESS: Felicia.McAroy@MarshMMA.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : National Fire Insurance Co of Hartford	20478
INSURER B : Transportation Insurance Company	20494
INSURER C : The Continental Insurance Company	35289
INSURER D : Continental Casualty Company	20443
INSURER E :	
INSURER F :	

INSURED
Revance Therapeutics, Inc.
1222 Demonbreun St.
Nashville TN 37203
REVANTHERA1

COVERAGES **CERTIFICATE NUMBER:** 222110112 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER	N	N	6013736464	5/10/2024	5/10/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG 	$ 1,000,000 $ 500,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ SEE BELOW $
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY	N	N	6013736478	5/10/2024	5/10/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) 	$ 1,000,000 $ $ $ $
C	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 5,000	N	N	6013736481	5/10/2024	5/10/2025	EACH OCCURRENCE AGGREGATE 	$ 10,000,000 $ 10,000,000 $
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below		N	6080725638	5/10/2024	5/10/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
D	Products Liability	N	N	ADT2048947127	5/10/2024	5/10/2025	Each Claim Aggregate Each Claim Deductible	$10,000,000 $10,000,000 $100,000

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

CERTIFICATE HOLDER

Evidence of Coverage

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 12BSBIL4789 ,

on behalf of Crown Laboratories, Inc.

of 207 Mockingbird Lane, Johnson City, TN 37604

in favor of Nevada State Board of Pharmacy

and in the amount of Twenty-Five Thousand ($25,000.00) Dollars.

It is understood and agreed that effective February 6, 2025

The principal name and address shall be changed

from Crown Laboratories, Inc.; 207 Mockingbird Lane Johnson City TN 37604

to Crown Laboratories, Inc. and Revance Therapeutics, Inc.; 1222 Demonbreun St, 20th Fl Nashville TN 37203

All other conditions and terms remain as originally written.

Signed. Sealed. and Dated February, 10th , 2025

Hartford Fire Insurance Company

By: Joelle L LaPierre , Attorney-in-Fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

Form GENCNG-A (Rev. 07/01/22)

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: HUB INTERNATIONAL NORTHEAST LTD
Agency Code: 12-122343

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 12BSBIL4789
Naming Crown Laboratories, Inc. and Revance Therapeutics, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of February 10, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Revance Therapeutics, Inc. MDEG License # (if applicable): N/A

Physical Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 615-724-7755 Website: www.revance.com

Licensing Company Email: mkorenberg@revance.com

Section 2: Personal Information

First: Marc Korenberg Middle: Andrew Last: Korenberg

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

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

Mailing Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Telephone: [redacted] Email: mkorenberg@revance.com

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

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

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

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

School Name	From - To (MM/YY – MM/YY)		
Keller Graduate School of Management of DeVry University	7/2008 -12/2011		
Address	**City**	**State**	**Zip**
4225 Naperville Rd, Suite 400,	Lisle	IL	60532
Diploma/Degree obtained, if any			
MBA, Finance			

School Name	From - To (MM/YY – MM/YY)		
University of Vermont	9/1995 - 12/1999		
Address	**City**	**State**	**Zip**
284 East Avenue, 284 E Ave	Burlington	VT	05405
Diploma/Degree obtained, if any			
BS, Business Administration			

School Name	From - To (MM/YY – MM/YY)		
Framingham High School	9/1991 - 6/1995		
Address	**City**	**State**	**Zip**
Winch Park, 115 A St.	Framingham	MA	01701
Diploma/Degree obtained, if any			
High School diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2023 - present	[redacted]	Brentwood	TN	[redacted]
12/2021 - 11/2023		Brentwood	TN	
12/2020 - 11/2021		Franklin	TN	
7/2018 - 11/2020		Pleasanton	CA	
9/2017 - 8/2018		Pleasanton	CA	
1/2012 - 8/2017		Pleasanton	CA	

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

Business Name	From - To (MM/YY – MM/YY)
Revance Therapeutics, Inc.	06/2020 - Present

Business Address	City	State	Zip
1222 Demonbreun Street, Suite 2000	Nashville	TN	37203

Phone	Title	Number of Employed Hours
615-724-7755	SVP, Finance	6,000+

Description of Duties

Oversee all operations for commercial organization including distribution, trade, and supply chain relationships With manufacturing partners internally and externally.

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Continue on next page if additional space is needed.

Business Name

From - To (MM/YY – MM/YY)

Business Address

City

State

Zip

Phone

Title

Number of Employed Hours

Description of Duties

Business Name

From - To (MM/YY – MM/YY)

Business Address

City

State

Zip

Phone

Title

Number of Employed Hours

Description of Duties

Business Name

From - To (MM/YY – MM/YY)

Business Address

City

State

Zip

Phone

Title

Number of Employed Hours

Description of Duties

Business Name

From - To (MM/YY – MM/YY)

Business Address

City

State

Zip

Phone

Title

Number of Employed Hours

Description of Duties

Business Name

From - To (MM/YY – MM/YY)

Business Address

City

State

Zip

Phone

Title

Number of Employed Hours

Description of Duties

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

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

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

This is in response to Question # [N/A]. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Marc Korenberg, **certify that as the MDEG Administrator for**

Revance Therapeutics, Inc.,

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

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

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

Marc Korenberg
Print Name (First, Last)

Marc Korenberg
Original Signature (electronic, copies or stamps not accepted)

10/29/24
Date

Board Use Only	Date Received: _____

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Revance Therapeutics, Inc.

Pharmacy/Wholesaler License # (if applicable): WH02864

Physical Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Mailing Address (if different from physical address): same as above

City: State: TN Zip: 37203

Telephone: 615-724-7755 Website: www.revance.com

Licensing Company Email: mkorenberg@revance.com

Section 2: Personal Information

First: Marc Middle: Andrew Last: Korenberg

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

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

Mailing Address: 1222 Demonbreun Street, Suite 2000

City: Nashville State: TN Zip: 37203

Telephone: [redacted] Email: mkorenberg@revance.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Keller Graduate School of Management of DeVry University			7/2008 -12/2011	
Address		City	State	Zip
4225 Naperville Rd, Suite 400		Lisle	IL	60532
Diploma/Degree obtained, if any				
MBA, Finance				
School Name			From - To (MM/YY – MM/YY)	
University of Vermont			9/1995 - 12/1999	
Address		City	State	Zip
284 East Avenue, 284 E Ave		Burlington	VT	05405
Diploma/Degree obtained, if any				
BS, Business Administration				
School Name			From - To (MM/YY – MM/YY)	
Framingham High School			9/1991 - 6/1995	
Address		City	State	Zip
Winch Park, 115 A St.		Framingham	MA	01701
Diploma/Degree obtained, if any				
High School diploma				
School Name			From - To (MM/YY – MM/YY)	
			/-/	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
			/-/	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2023 - present	[redacted]	Brentwood	TN	[redacted]
12/2021 - 11/2023		Brentwood	TN	
12/2020 - 11/2021		Franklin	TN	
7/2018 - 11/2020		Pleasanton	CA	
9/2017 - 8/2018		Pleasanton	CA	
1/2012 - 8/2017		Pleasanton	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Revance Therapeutics, Inc.			4/2018 - Current	
Business Address		City	State	Zip
1222 Demonbreun Street, Suite 2000		Nashville	TN	37203
Phone	Title		Number of Employed Hours	
(615) 724-7755	SVP, Finance		6,000+	
Description of Duties				
Oversee all operations for commercial organization including distribution, trade, and supply chain relationships With manufacturing partners internally and externally.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

N/A

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Marc Korenberg, **certify that as the designated representative for**

Revance Therapeutics, Inc.,

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

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

Marc Korenberg

Print Name (First, Last)

Marc Korenberg

Original Signature (electronic, copies or stamps not accepted)

10/29/24

Date

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

Marc Korenberg

Print Name (First, Last)

Marc A Korenberg

Original Signature (electronic, copies or stamps not accepted)

10/29/24

Date

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

State of Tennessee, ss. County of Davidson

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

Marc A. Korenberg

Original Signature

Date 10/29/24

Subscribed and Sworn to before me this 29 day of October, 2024

Kathleen M Warner

Notary Public Signature

KATHLEEN M. WARNER
STATE OF TENNESSEE NOTARY PUBLIC
WILLIAMSON COUNTY
(Seal)

Employees

Please Keep Confidential

Revance Therapeutics, Inc.

Corporate Officer:

Jeffery A. Bedard
CEO

Designated Representative:

Marc Korenberg

Other Employees:

Crain, Allison
Gibbs, Mary
Wallace, Essence
Pilgrom, Gregory
Kohler, Sadie
Atalla, Isabel
Haney, Ashleigh M
Mendoza, Karmen
Maclaren, Kristy
Paul, Edwin
Harris, Brian
Buechele, Keith
Kudelko, Caroline
Warner, Kathleen
Lindsay, Christina Scholz
Slaughter, Marlene
Anglin, Marvie
Hall, Lauren
Patel, Gaurang
South, Hannah
Cruse, Brian D
Thompson, Olivia D
Deeb, Dara
Sorensen, Sutton B.
Pemberton, Hilary J
Britton, Emily
Craig, Elizabeth A
Smith, Kelly J
Lafferty, Jennifer L

Svalstedt, Lisa C
Mira, Joseph
Sheft, Kristen
Hiera, Sean
Fink, Britney
Woodie, Ashtin
Martinez, Maria D
George, Karen Hensley
De Sousa, Igor
Torreon, Andrew P
Sites, Christin M
Kiteck, Albert W
Hanna, Parker
Selvaraj, Senthilkumar
Richards, Ryan S
Tao, Dongying
Jones, Mark S
Krause, Amie
Holladay, Katelyn
McKnight, Jonathan R
Stephenson, Jason
Stewart, Robert
Davis, Kerrielle
McCraw, John
Jordan, Erica
Beagle, Brynne
Finner, Abbie
Bogee, Leona
Redfield-Stolzenburg, Hillary
Jones, Brian
Berg, Kevin
Hershey, Olivia
Iannozzi, Jason Anthony
Cauley, Melissa
Boeckmann, Meredith
Burnich, Stephen
Bell, Samantha
Singh, Siddhartha
Jones, Vivian
Kowalski, Curt
Parker, Jennifer
Powell, Sarah
McKernan, Kevin
Briggs, Alexa
Glenn, Eric
Blackburn, David P
Biotti, Reagan M
Morrison, Alexis M
Bateman, Abigail F

Wyche, Carolyn
Nautiyal, Rakesh
Todd, Julie
Determann, Cory
Wood, Heather

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/26/2017	7/15/2019	AL	Birmingham	Jefferson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
18-L-0111	Alabama Board of Pharmacy

Reason/Charge
Alleged violation of FDA Act 21 USC Sec 331(a)(d)(k)

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On July 15, 2019, the Alabama Board of Pharmacy fully executed a Consent Order (referred to as the "Consent Order") to resolve In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. 192569, Case No. 18-L-0111 before the Alabama Board of Pharmacy. In the Consent Order, "[c]ounsel for the parties stipulate that Crown denies for all legal purposes other than this proceeding the allegations set forth in the Statement but further stipulate the Board would introduce sufficient evidence to prove Crown (a) entered into the Consent Decree of Permanent Injunction filed in the United States District Court, E.D. Tenn., 2: l 7-cv-36, dated July 26, 2017, and attached to the Statement (the 'Consent Decree'), (b) is required to comply with the Consent Decree in that federal action, and (c) is required to comply with the Consent Decree as part of this Consent Order in this action."

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/29/2021	3/29/2021	AR	Little Rock	Pulaski

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2020-133	Arkansas State Board of Pharmacy

Reason/Charge
Board regulation 08-00-0003 and ACA sec 17-92-107 and sec 17-92-315

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On March 29, 2021, the Arkansas Board of Pharmacy fully executed a non-disciplinary Consent Agreement to resolve In The Matter of: Crown Laboratories, Inc. Wholesale Distributor License No. WD04403, Case No. 2020- 133 before the Arkansas State Board of Pharmacy. In the Consent Agreement, Crown Laboratories, Inc. agreed to pay a non-disciplinary investigative cost for not reporting the change in ownership within the time frame specified in Arkansas Pharmacy Board Regulation 04-04-0001. The Consent Agreement was fully executed on March 29,2021 by the Arkansas Board of Pharmacy, but Crown Laboratories was notified of this execution on July 22, 2021. Please see the attached letter from the Arkansas Board of Pharamcy for verification of the received date.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/02/2020	3/02/2020	AZ	Phoenix, AZ	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
20-0050	Arizona Board of Pharmacy

Reason/Charge
Late ownership change notification. AAC R4-23-601(F)

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On March 2, 2020, the Arizona Board of Pharmacy fully executed a Consent Agreement and Order for Civil Penalty (referred to as the "Consent Agreement") to resolve In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. M001475, Case No. 20-0050 before the Arizona Board of Pharmacy. In the Consent Agreement, Crown Laboratories, Inc. agreed to pay a civil penalty for not reporting the change in ownership within the time frame specified in Arizona Administrative Code (A.A.C.) R4-23-601(F).

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/18/2021	6/10/2021	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-0990	Colorado Board of Pharmacy

Reason/Charge
Alleged violation of state statute 12-280-126

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On June 7, 2021, Colorado Department of Regulatory Agencies notified Crown Laboratories, Inc. of a Stipulation and Final Agency Order (referred to as the "Order"). To resolve In The Matter of: Crown Laboratories, Inc., Registration No. WHO.7991, Case No. 2021-0990 before the Colorado State Board of Pharmacy. In the Order, Crown agreed to resolve the case by means of a stipulated agreement with paying the fine for not reporting the change in ownership within the time frame specified in sections 12-280-126 of Colorado Revised Statues. The Stipulation and Final Agency Order was approved and became effective on June 10, 2021.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/16/2022	7/15/2022	FL	Tallahassee	Leon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2020-011437	Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics

Reason/Charge
Alleged violation of state statute 499.012(6)

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On May 16, 2022, the Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics and Crown Laboratories, Inc. entered into a Settlement Agreement, Case No. 2020-011437. In the Settlement, Crown Laboratories, Inc. agreed to resolve the case by means of a settlement amount for not reporting the change in ownership and applying for a new permit within the time frame specified in section 499.012(6), Florida Statutes (2017-2019). The Final Order was approved and became effective on July 15, 2022.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/21/2021	7/21/2021	ME	Augusta	Kennebec

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-PHA-17245 & 17246	Maine Board of Pharmacy

Reason/Charge
Violation of state rule 12 § 5.

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On July 21, 2021, the Maine Board of Pharmacy fully executed Consent Agreements and Orders for Civil Penalties (referred to as the "Consent Agreements") to resolve In Matter of: Crown Laboratories, Inc., Case No. 2021-PHA-17245 and 17246 before the Maine Board of Pharmacy. In the Consent Agreements, Crown Laboratories, Inc. agreed to pay a civil penalty for not reporting the change in ownership within the time frame specified in Maine Board Rules Chapter 12 § 5.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/4/2022	3/4/2022	MO	Jefferson City	Coal

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	Missouri Board of Pharmacy

Reason/Charge
Alleged violation of state law 144.083.2

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

On March 04, 2022, Crown Laboratories, Inc.'s Missouri Drug Distributor Registrant License was revoked due to an issue with the Missouri Department of Revenue and sales tax return filings for the company. The revocation of the license was not due to any illegal distribution activity, nor any quality issues with any drug products. The tax issues have been resolved with the Department of Revenue and a new license has been issued as Crown Laboratories, Inc. is back in good standing with the Missouri Department of Revenue.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. See Attachment K

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/1/2017	7/25/2017	TN	Greeneville, TN	Greene

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:17-cv-36	US District Court for the Eastern District of Tennessee

Reason/Charge
Alleged violation of FDA Act 21 USC Sec 331(a)(d)(k)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
United States of America v. Crown Laboratories, Inc., and Jeffery Bedard	N/A

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

The matter was settled and all product was destroyed.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. No documentation available

This is in response to Question # 3 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/15/2020	4/15/2020	NH	Concord	Merrimack

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	New Hampshire Board of Pharmacy

Reason/Charge
Alleged violation of state law RSA 318:51-a, V and Ph I 002.12

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

Name of Business/Industry/Entity
Crown Laboratories, Inc.

Provide explanation below:

At its April 15, 2020 Meeting, the New Hampshire Board of Pharmacy ("Board") reviewed the change of ownership application submitted by Crown Laboratories, Inc. on March 31, 2020. While reviewing the application, the Board noted that the application included documentation of disciplinary action in Alabama and Arizona from 2019 and 2020. This discipline had not been previously reported to the New Hampshire Board of Pharmacy. Per RSA 318:51-a, V and Ph I 002.12, the Board must be notified within 30-days of any changes, including disciplinary action in other states. Accordingly, the Board sees fit to assess an administrative fine of $150.00. This fine shall be a non- disciplinary, administrative fine.

Original Signature (electronic, copies or stamps not accepted)

10/21/2024
Date

Attachment K

Disciplinary Action Documentation

CROWN
SKIN SCIENCE FOR LIFE

Alabama Disciplinary Action

On July 15, 2019, the Alabama Board of Pharmacy fully executed a Consent Order (referred to as the "Consent Order") to resolve *In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. 192569*, Case No. 18-L-0111 before the Alabama Board of Pharmacy. In the Consent Order, "[c]ounsel for the parties stipulate that Crown denies for all legal purposes other than this proceeding the allegations set forth in the Statement but further stipulate the Board would introduce sufficient evidence to prove Crown (a) entered into the Consent Decree of Permanent Injunction filed in the United States District Court, E.D. Tenn., 2:17-cv-36, dated July 26, 2017, and attached to the Statement (the 'Consent Decree'), (b) is required to comply with the Consent Decree in that federal action, and (c) is required to comply with the Consent Decree as part of this Consent Order in this action."

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
CROWN LABORATORIES, INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer Permit No. 192569	)	**CASE NO: 18-L-0111**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Crown Laboratories, Inc.
349 Lafe Cox Drive
Johnson City, Tennessee 37604

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 16, 2019 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Crown Laboratories, Inc. (Crown) as a Manufacturer should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted based upon any or all of the following:

COUNT ONE

The Complaint for Permanent Injunction and/or the Consent Decree of Permanent Injunction attached hereto cumulatively as Exhibit "A" in a case styled United States of America v. Crown Laboratories, Inc. et al. in the United States District Court for the Eastern District of Tennessee, Civil Action 2:17-cv-36.

The Board alleges that each complained of act in deviation of 21 USC 331(a), (d) or (k) as alleged in the Complaint or Consent Decree is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 14th day of January, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. CROWN LABORATORIES, INC., a corporation and JEFFERY BEDARD, an individual, Defendants.	Civil Action No.: _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Crown Laboratories, Inc. ("Crown" or "the firm") is a corporation incorporated and registered to do business in Tennessee. Crown operates at its principal place of business and drug manufacturing facility, which is located at 349 Lafe Cox Drive, Johnson City, Tennessee (the "Facility"), within the jurisdiction of this Court.

5. Crown manufactures, processes, packs, labels, holds, and distributes a variety of prescription and over-the-counter ("OTC") drugs including, but not limited to, prescription urea cream and lotion, and prescription Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), which are the subject of this action. Specifically, Crown manufactures, processes, packs, labels, holds, and distributes in interstate commerce Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) under its own labels. Crown also manufactures, processes, packs, labels, holds, and distributes in interstate commerce Sodium Sulfacetamide as a contract manufacturer for another pharmaceutical firm.

6. Defendant Jeffery Bedard is Crown's Chief Executive Officer. He is responsible for, and has authority over, all operations at the firm. He has the authority and duty to prevent, detect, and correct objectionable conditions. He performs his duties at the Facility, within the jurisdiction of this Court.

DEFENDANTS' VIOLATIONS OF THE ACT

Unapproved New Drugs

7. A product is a drug within the meaning of the Act, inter alia, if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

8. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

9. The products Defendants introduce or deliver for introduction into interstate commerce are drugs within the meaning of the Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and/or intended to affect the structure or any function of the body of man. Specifically, according to the products' labels, Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) are intended to treat hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratosis, and calluses, and Sodium Sulfacetamide is intended to treat acne vulgaris, acne rosacea, and seborrheic dermatitis.

10. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or any drug . . the

composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p).

11. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver, or cause to be introduced or delivered, into interstate commerce a new drug that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

12. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are "new drugs" within the meaning of the Act, inter alia, because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. § 321(p)(1).

13. There is no application under 21 U.S.C. § 355 on file with FDA for Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), or Sodium Sulfacetamide that would allow Crown to introduce or deliver these products, or cause them to be introduced or delivered, into interstate commerce to the public.

14. Defendants' introduction or delivery for introduction of these drug products into interstate commerce therefore violates 21 U.S.C. § 331(d).

Misbranded Drugs

15. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

16. A drug is misbranded if its labeling fails to bear "adequate directions for use," and does not fall within a regulatory exemption from this requirement. 21 U.S.C. § 352(f)(1); 21 C.F.R. Part 201, Subpart D.

17. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(B). The labeling of these products state that they are intended for "Rx Only" use.

18. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are misbranded because they do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.100 or 201.115. A new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its approved application. See 21 C.F.R. § 201.115. Moreover, a prescription drug that is a new drug can qualify for the exemption from the adequate directions for use requirement if its labeling bears the information authorized by an approved new drug application. See 21 C.F.R. § 201.100(c)(2). New drugs that lack an approved NDA, such as Defendants' prescription drugs, cannot qualify for either of these exemptions and therefore are misbranded as a matter of law.

19. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

20. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug, as defined by 21 U.S.C. § 321(g)(1), to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Interstate Commerce

21. During the most recent inspection of the Facility between February 22 and 25, 2016, FDA documented Defendants' shipment of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion to Georgia and Utah, and of Dermasorb XM Trade Kit (Urea 39% Cream and Moisturizer) to California. FDA also documented Defendants' shipment of Sodium Sulfacetamide to Ohio. These shipments constitute the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. §§ 331(a) and (d).

22. Defendants receive raw materials from outside of Tennessee, which they use to manufacture their drug products. For example, Defendants receive the active pharmaceutical ingredients Urea USP from Ohio and Sodium Sulfacetamide Monohydrate from Mississippi. Therefore, the interstate commerce element under 21 U.S.C. § 331(k) is met.

HISTORY

23. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

24. During a meeting with Defendants on December 2, 2015, FDA notified

Defendants that unapproved, marketed drugs are not listed in the FDA Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, (35th ed. 2015), which is a compilation of drugs approved by FDA on the basis of safety and effectiveness whose applications have not been withdrawn or suspended for safety or effectiveness reasons and FDA's evaluations on the therapeutic equivalence of drugs, and that the marketing of these products absent an approved application may violate the Act and subject them compliance action.

25. During an inspection of the Facility between March 2 and 3, 2015, FDA documented Defendants' distribution in interstate commerce of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion. By letter dated May 13, 2015, FDA explained to then counsel for Defendant Crown that 40% Urea Cream, 40% Urea Lotion, 39% Urea Lotion, and Sodium Sulfacetamide are new drugs that are subject to the Act's premarket approval requirement.

26. During an inspection of the Facility between February 10 and 14, 2014, FDA documented, among other things, Defendants' manufacturing and distribution in interstate commerce of prescription urea drugs privately labeled for Ascend Laboratories, LLC (hereafter, "Ascend"), specifically products labeled as Ascend Urea Cream 40% and Ascend Urea 40% Lotion. FDA also documented Defendants' manufacturing and distribution in interstate commerce of Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) and Sodium Sulfacetamide during the inspection. The FDA investigator discussed the potential unapproved status of these drugs with firm management, including Defendant Bedard, and made them aware of FDA's Compliance Policy Guide Section 440.100, Marketed New Drugs Without Approved NDAs or ANDAs, amended September 19, 2011 ("CPG Section 440.100"); see also 76 Fed. Reg. 58398-01 (Sept. 21, 2011). In CPG Section 440.100, FDA notified manufacturers and

distributors that any product that is being illegally marketed is subject to enforcement at any time and that all unapproved drugs introduced onto the market after September 19, 2011, are subject to immediate enforcement action without prior notice and without respect to the enforcement priorities listed therein. See also 76 Fed. Reg. at 58399.

27. In May 2014, the United States conducted a seizure of certain unapproved and misbranded drugs that were being distributed by Ascend, including but not limited to the urea drug products that Defendants had manufactured for Ascend (Ascend Cream Urea 40% Cream, Ascend Urea Lotion 40%, and Ascend Urea Cream 39%). The United States notified Defendants of the seizure by letter dated May 15, 2014.

28. Defendant Bedard stated, by letter dated March 5, 2014 to FDA, that Crown "does not currently plan to file an NDA for any of these products . . . ." During FDA's February 2016 inspection, the firm's Vice President of Quality Assurance and Quality Control, stated that he believes that the products at issue are legal drug products and that they will continue to be manufactured and shipped in the future.

29. Accordingly, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (d), and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drug, including but not limited to Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredients, unless and until an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, all Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredient(s) in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect Defendants' place(s) of business and all

records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 1st day of March, 2017.

Respectfully submitted,

Of Counsel:

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. CROWN LABORATORIES, INC., a corporation and JEFFERY BEDARD, an individual, Defendants.	Civil Action No.: 2:17-cv-36 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. §§ 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. Introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce, manufacturing, processing, packaging, labeling, holding, or selling any Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), or any drug labeled similarly to such drugs and containing the same active ingredient(s), unless and until an approved new drug application or an abbreviated new drug application or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs;

B. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is a new drug within the meaning of 21 U.S.C. § 321(p) and that is neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under to 21 U.S.C. § 355(i);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

D. Violating of 21 U.S.C. § 331(k) by, directly or indirectly, causing any drug that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Directly or indirectly causing to be done any act that results in the failure to implement and continuously maintain the requirements of this Decree.

Nothing in this paragraph or paragraph 7 or paragraph 9 shall preclude Defendants from marketing a drug subject to an ongoing Drug Efficacy Study Implementation (DESI) proceeding during the pendency of that proceeding. The preceding sentence does not apply when a DESI proceeding closes. No provision of this Decree shall affect the authority of the United States to bring an action against Defendants for a violation of the Act and/or its implementing regulations.

7. A. Within twenty (20) business days after entry of this Decree, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy all Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide, any unapproved drug labeled similarly to such drugs and containing the same active ingredient(s), and any unapproved new drugs not expressly listed herein, in Defendants' custody, control, or possession (hereinafter, "Violative Drugs"). Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction.

B. Defendants shall at all times, until all of the Violative Drugs have been destroyed in accordance with this Decree, retain the Violative Drugs intact for examination or inspection by FDA at their facility at 349 Lafe Cox Drive, Johnson City, Tennessee ("the Facility"), and shall maintain all records or other proof necessary to establish the identity of the Violative Drugs to FDA's satisfaction. Defendants shall not cause the Violative Drugs to be

disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed.

C. Within fifteen (15) business days after receiving authorization from FDA to commence destroying the Violative Drugs, Defendants shall, under FDA supervision, complete the destruction in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in Paragraph 13, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

8. FDA shall be permitted, without prior notice and as FDA deems necessary, to make inspections of Defendants' place(s) of business (including, but not limited to, the Facility) and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate

corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all unapproved or misbranded drugs;

B. Recall, at Defendants' expense, any drugs that are unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; or

F. Take any other corrective actions with respect to unapproved or misbranded drugs as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

10. Any order issued by FDA pursuant to Paragraph 9 shall be issued by the appropriate FDA District Director, and shall specify the deficiencies or violations giving rise to the order. Unless a different time frame is specified by FDA in its order, within five (5) business days after receiving an order pursuant to Paragraph 9, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking, or have undertaken, the specified corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and a proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

A. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

B. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order unless the Court stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this subparagraph shall be made in accordance with the terms set forth in Paragraph 19.

C. The process and procedures set forth in Paragraph 10.A-B shall not apply to any order issued under Paragraph 9 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while implementing the order.

11. Any action ordered pursuant to Paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 9 shall be borne by Defendants at the rates specified in Paragraph 13.

12. The prohibitions set forth in Paragraphs 6 and 7 or in any order issued under Paragraph 9 shall not apply to any drug manufactured solely for export and/or exported from the United States, provided that all applicable requirements of the Act, including 21 U.S.C. §§ 381(e) and 382, and its implementing regulations have been satisfied with respect to such drug.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $90.65 per hour or fraction thereof per representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Facility, at any other location at which Defendants conduct business, and on Crown Laboratories, Inc.'s website, and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

15. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (hereafter collectively referred to as "Associated Persons"). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any Defendant becomes associated

with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Crown Laboratories, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

19. All decisions specified in this Decree shall be vested in FDA's discretion and shall be final. If contested by Defendants, FDA's decisions under this Decree shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the case name and civil action number, be prominently marked "Decree Correspondence" and "Crown Laboratories, Inc." and be addressed to:

District Director
New Orleans District Office
U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2565

21. Should Defendants fail to comply with any provision of this Decree, then they shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues, an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation of this Decree, and an additional sum equal to three (3) times the retail value of each shipment of an unapproved new drug and/or a misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017.

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

For Plaintiff

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

MICHAEL S. BLUME
Director
Consumer Protection Branch

JEFFERY BEDARD
Individually and on behalf of
Crown Laboratories, Inc.

/s/

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., Suite 6400 South
Washington, DC 20001
Telephone: 202-307-0088
Fax: 202-514-8742
Megan.Englehart@usdoj.gov

24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

JEFFERY BEDARD
Individually and on behalf of
Crown Laboratories, Inc.

For Plaintiff

[redacted]

MARY M. ENGLEHART
Trial Attorney
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U.S. Department of Justice
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Daniel G. Jarcho
Attorney for Jeffery Bedard

Daniel G. Jarcho
Attorney for Crown Laboratories, Inc.

OF COUNSEL:

JEFFREY S. DAVIS
Acting General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
Food and Drug Division

SUSAN WILLIAMS
Associate Chief Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301-348-3010

Daniel G. Jarcho
Attorney for Jeffery Bedard

Daniel G. Jarcho
Attorney for Crown Laboratories, Inc.

OF COUNSEL:

[redacted]
Acting General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
Food and Drug Division

SUSAN WILLIAMS
Associate Chief Counsel for Enforcement
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301-348-3010

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
CROWN LABORATORIES, INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer Permit No. 192569	)	**CASE NO: 18-L-0111**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Crown Laboratories, Inc. (hereinafter referred to as "Crown") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. Counsel for the parties stipulate that Crown denies for all legal purposes other than this proceeding the allegations set forth in the Statement but further stipulate the Board would introduce sufficient evidence to prove Crown (a) entered into the Consent Decree of Permanent Injunction filed in the United States District Court, E.D. Tenn., 2:17-cv-36, dated July 26, 2017, and attached to the Statement (the "Consent Decree"), (b) is required to comply with the Consent Decree in that federal action, and (c) is required to comply with the Consent Decree as part of this Consent Order in this action.

2. Crown shall pay to the Board administrative costs in the amount of Ten Thousand dollars ($10,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be

dischargeable in bankruptcy and Crown shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Crown expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Crown further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Crown hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Crown agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Crown acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Crown acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 11th day of July, 2019

Crown Laboratories, Inc.

By: _____
J.S. "Chris" Christie, Jr.
Its: Attorney at Law

DONE this the 15th day of July, 2019

ALABAMA STATE BOARD OF PHARMACY

By: _____
Kenny Saunders, R.Ph., President

By: _____
James S. Ward
Its Attorney

Ward & Cooper, LLC
2100 South Bridge Parkway
Suite 580
Birmingham, Alabama 35209

CROWN

SKIN SCIENCE FOR LIFE

Arizona Disciplinary Action

On March 2, 2020, the Arizona Board of Pharmacy fully executed a Consent Agreement and Order for Civil Penalty (referred to as the "Consent Agreement") to resolve *In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. M001475*, Case No. 20-0050 before the Arizona Board of Pharmacy. In the Consent Agreement, Crown agreed to pay a civil penalty for not reporting the change in ownership within the time frame specified in Arizona Administrative Code (A.A.C.) R4-23-601(F).

MARK BRNOVICH
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **Crown Laboratories, Inc.** Applicant for Pending Permit No. M001475 As a Non-Resident Manufacturer In the State of Arizona. Applicant.	Board Case No. 20-0050 **CONSENT AGREEMENT AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Crown Laboratories, Inc. ("Applicant"), Applicant for issuance of Pending Non-Resident Manufacturer Permit no. M001475 in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Applicant has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Applicant understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Applicant knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Applicant affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Applicant understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Applicant understands this Consent Agreement deals with allegations of unprofessional conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's adoption of this Consent Agreement.

6. Applicant understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Applicant also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

8. Applicant acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke its acceptance of the Consent Agreement or make any modifications to the document. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Applicant shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. Applicant understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(19) and A.R.S. § - 1927.02(A)(1).

14. Applicant agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY APPLICANT

Marie Fagarie Dated: 02/26/2020

On behalf of Crown Laboratories, Inc.

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Applicant is seeking the issuance of permit number M001475, which will allow it to operate as a Non-Resident Manufacturer in the State of Arizona. Applicant is located at 349 Lafe Cox Drive, Johnson City, TN 37604.

3. Applicant previously held Manufacturer Permit no. M000641 under prior ownership, which was initially issued on October 7, 2013.

4. The Board possesses jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

5. Pursuant to Arizona Administrative Code (A.A.C.) R4-23-601(F), at least 14 days before a change in ownership of a permit, the new permittee shall apply to the Board for a new license or permit.

6. On October 2, 2019, Board staff received a change of ownership application for pharmacy permit number M00641. According to documentation obtained

by the Board, the change of ownership had occurred on January 16, 2018.

CONCLUSIONS OF LAW

1. The Board possesses subject matter and personal jurisdiction over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may deny a permit to an applicant that has engaged in unprofessional conduct. A.R.S. § 32-1927.02(P).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(18) (violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of the Pharmacy Act) as it relates to A.A.C. R4-23-601(F) and A.A.C. R4-23-607(D) (which requires non-resident permittees to make application to the Board at least 14 days before there is a change in ownership).

ORDER

Based on the Findings of Fact and Conclusions of Law and pursuant to the authority granted to the Board under A.R.S. § 32-1927.02:

1. **IT IS HEREBY ORDERED** Applicant shall pay to the Board as a civil penalty the sum of Two Hundred Fifty Dollars (**$250.00**). The civil penalty shall be paid in full to the Board within **sixty (60) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. **The permit shall not issue until such time Applicant pays the civil penalty as set forth above.** Within five (5) business days of the receipt of the $250.00 civil penalty, the Board shall issue Applicant a Non-Resident Manufacturer Permit.

3. **Should Applicant fail to pay the civil penalty as set forth above within sixty (60) days of the effective date of the Consent Agreement and Order, the**

application shall automatically be denied. The effective date of this Consent Agreement and Order is the date it is signed by the Board's Executive Director or his designee.

4. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

5. If Applicant violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Applicant notice and the opportunity to be heard, may revoke, suspend or take other disciplinary actions against Applicant's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 2nd day of March, 2020.

ARIZONA STATE BOARD OF PHARMACY

By: Elizabeth Dodge, Deputy Director for
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 2nd day of March, 2020, with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED
BY CERTIFIED & REGULAR FIRST-CLASS MAIL
this 2nd day of March, 2020, to:

Crown Laboratories, Inc.
349 Lafe Cox Drive
Johnson City, TN 37604

COPY OF THE FOREGOING MAILED this 2nd day of March, 2020 to:

Jeanne M. Galvin
Seth T. Hargraves
Assistant Attorney General
2005 North Central Ave., SGD/LES
Phoenix, Arizona 85004
Attorneys for the State

Doc#8519750

CROWN

SKIN SCIENCE FOR LIFE

Arkansas Disciplinary Action

On March 29, 2021, the Arkansas Board of Pharmacy fully executed a non-disciplinary Consent Agreement to resolve *In The Matter of: Crown Laboratories, Inc. Wholesale Distributor License No. WD04403*, Case No. 2020-133 before the Arkansas State Board of Pharmacy. In the Consent Agreement, Crown agreed to pay a non-disciplinary investigative cost for not reporting the change in ownership within the time frame specified in Arkansas Pharmacy Board Regulation 04-04-0001. The Consent Agreement was fully executed on March 29,2021 by the Arkansas Board of Pharmacy, but Crown Laboratories was notified of this execution on July 22, 2021. Please see the attached letter from the Arkansas Board of Pharamcy for verification of the receival date.

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

July 22, 2021

Crown Laboratories, Inc.
349 Lafe Cox Drive
Johnson City, TN 37604

VIA EMAIL

RE: Consent Agreement

Dear Sir Madam:

The Arkansas State Board of Pharmacy is providing you with the signed executed copy of the consent agreement today, July 22, 2021.

Should you wish to discuss this matter further, please contact Deputy Director Brenda McCrady or myself at (501) 682-0190.

Sincerely,

Luke Daniel
ASBP General Counsel

Enclosure

ARKANSAS STATE
BOARD OF PHARMACY
MAR 29 2021
RECEIVED

BEFORE THE ARKANSAS STATE BOARD OF PHARMACY

IN THE MATTER OF
CROWN LABORATORIES, INC.
WD04403 **CASE # 2020-133**

CONSENT AGREEMENT

WHEREAS, Respondent **Crown Laboratories Inc.** located in Johnson City, Tennessee, is licensed as a wholesale distributor of prescription drugs and holds license number WD04403;

WHEREAS, a change of ownership occurred on October 13, 2017. The Board did not receive notification from Respondent **Crown Laboratories Inc.** of said change of ownership until December 4, 2020.

WHEREAS, Crown Laboratories Inc. may be charged with violations of Board Regulation 08-00-0003 and A.C.A. §17-92-407, and § 17-92- 315;

WHEREAS, Respondent makes no admission of guilt but wishes to resolve these charges informally. By entering into this non-disciplinary Consent Agreement, Respondent's statements herein shall not be used as evidence in a formal hearing if this agreement is not accepted by the Board. Respondent and the Board therefore agree that this Agreement shall not constitute disciplinary action but rather an informal resolution of these charges. Respondent expressly waives its right to an administrative hearing and consents to the terms incorporated in this Agreement. Respondent further consents to the *ex parte* presentation of this Agreement to the Board and agrees that, if the Agreement is not accepted by the Board, the presentation and consideration of this Consent Agreement by the Board shall not constitute a basis for disqualification of the Board or any of its members from further participation in this matter, including a formal hearing; and

WHEREAS, Respondent acknowledges that this Consent Agreement is not effective until its acceptance by the Board, that Respondent has had the opportunity to consult with legal counsel of its own choosing concerning the advisability, meaning and effect of this Consent Agreement, that the Board shall retain jurisdiction to enforce the provisions of this Consent Agreement, and that failure to comply with the terms and conditions of this agreement shall be grounds for disciplinary action in the form of a civil penalty and/or suspension or revocation of Respondent's license, registration or permit.

THEREFORE, Respondent consents to the following terms in full resolution of this complaint:

1. Respondent **Crown Laboratories Inc. (WD04403)** willingly agrees and stipulates that it shall pay a non-disciplinary investigative cost of two thousand five hundred dollars ($2,500.00) to the Board on or before February 28, 2021

EXECUTED this 25th day of March, 2021

Authorized Representative of Crown Laboratories Inc.
Respondent

Attorney for Respondent (Optional)

John Clay Kirtley
Executive Director
Arkansas State Board of Pharmacy

President
Arkansas State Board of Pharmacy

CROWN
SKIN SCIENCE FOR LIFE

Colorado Disciplinary Action

On June 7, 2021, Colorado Department of Regulatory Agencies notified Crown of a Stipulation and Final Agency Order (referred to as the "Order"). To resolve In The Matter of: Crown Laboratories, Inc., Registration No. WHO.7991, Case No. 2021-0990 before the Colorado State Board of Pharmacy. In the Order, Crown agreed to resolve the case by means of a stipulated agreement with paying the fine for not reporting the change in ownership within the time frame specified in sections 12-280-126 of Colorado Revised Statues. The Stipulation and Final Agency Order was approved and became effective on June 10, 2021.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2021-0990

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF CROWN LABORATORIES, INC., REGISTRATION NO. WHO. 7991,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Crown Laboratories, Inc. ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2021-0990, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as a non-resident wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 280, C.R.S. (2019).

2. Respondent Outlet was originally registered in the State of Colorado on or about October 9, 2013, being issued registration number WHO.7991, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 349 Lafe Cox Dr, Johnson City, TN 37604.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a transfer of ownership and fee. In this case, 1, 102 days transpired between October 13, 2017, the date the previous designated representative ceased the position, and October 19, 2020, the date the application and fee were received.

6. On or about February 18, 2021, the Board initiated a complaint against Respondent Outlet because of the delay of 1,102 days in submitting an application detailing a change of ownership and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board; or

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.
b. Any change in ownership shall be reported on an application provided by the Board within thirty (30) days prior to the change, with a final notice of the ownership change reported to the Board the day of such change. The new owner(s) shall pay the appropriate fee. A change of ownership shall be deemed to have occurred:

(1) In the event the owner is a corporation, upon sale or transfer of twenty percent or
more of the shares of the corporation to a single individual or entity;

(2) In the event the outlet is owned by a partnership, upon sale or transfer of twenty
percent or more of any ownership interest.

3) In the event the outlet is owned by a limited liability company (LLC), upon sale or
transfer of twenty percent or more of the membership interests.

(4) Upon incorporation of an existing wholesaler.

8. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

9. **Fine with Surcharge.** Pursuant to section 12-280-127(5)(a), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand, One Hundred, and Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

10. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in its ownership within the required time frame specified by Board rule or statute in effect at the time of such designated ownership change.

11. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

12. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-20-403, 12-280-126, and 12-280-127, C.R.S.; and

    d. to appeal this Final Agency Order.

Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

13. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

14. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-280-127(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Crown Laboratories, Inc.

Dated: 06/08/2021

Authorized Representative

Calvin Taylor / Vice President of Quality and Regulatory

Name/ Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 10 day of June, 2021.

State Board of Pharmacy

BY: _____

Dmitry Kunin

Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 10th day of June 2021, addressed as follows:

Crown Laboratories, Inc.
349 Lafe Cox Dr
Johnson City, TN 37604-7469

Linda Stanko
Agent of the Board

CROWN
SKIN SCIENCE FOR LIFE

Florida Disciplinary Action

On May 16, 2022, the Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics and Crown entered into a Settlement Agreement, Case No. 2020-011437. In the Settlement, Crown agreed to resolve the case by means of a settlement amount for not reporting the change in ownership and applying for a new permit within the time frame specified in section 499.012(6), Florida Statutes (2017-2019). The Final Order was approved and became effective on July 15, 2022.

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK: Brandon Nichols
Date: 7/21/2022
File #: 2022-05874

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2020-011437**

CROWN LABORATORIES, INC.,

Respondent,
_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Crown Laboratories, Inc. and the Department, attached hereto and incorporated by reference. This Final Order resolves alleged violations of Section 499.012(6), Florida Statutes (2017-2019), failing to make application for a new permit after a majority change of ownership occurred and continuing to operate.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department as indicated on this Final Order.

DONE and ORDERED this 15th day of July, 2022 in Tallahassee, Florida.

MELANIE S. GRIFFIN, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Walter S. Copeland, Director
Division of Drugs, Devices, and Cosmetics

Prepared by:

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by electronic mail to: James Lawrence, jlawrence@envisage.law, on this 21st day of July, 2022.

By: Brandon M. Nichols
Agency Clerk's Office

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2020-011437**

v.

CROWN LABORATORIES, INC.,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2020-011437 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Crown Laboratories, Inc. (hereinafter, "Respondent") failed to timely file notification of transfer of ownership with the Department.

2. Respondent's address of record is 3349 Lafe Cox Drive, Johnson City, Tennessee 37604.

3. Respondent was issued a Notice of Violation on June 22, 2022, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2020-011437, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent agrees to comply with Chapter 499, Florida Statutes, and the administrative rules adopted under the statute, in the future.

7. Respondent agrees to pay a settlement amount of fifteen thousand dollars ($15,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. Respondent affirms that the violation alleged in the Notice of Violation letter issued in case number 2020-011437 has been corrected.

9. The Department agrees that this agreement will not be deemed to constitute discipline against the Respondent within the meaning of Section 499.066, Florida Statutes, and Rule 61N-1.024, Florida Administrative Code, and that this agreement will not be considered in

any future claim, action or proceeding against Respondent by the Department. The Department will not deny or seek to deny any application for a permit of Respondent based on the allegations. Nothing herein shall be construed to limit, restrict or otherwise affect the Department's rights to (i) inspect under Section 499.051, Florida Statutes, (ii) examine, sample, test, embargo, seize, detain, condemn or destroy any drug, device, or cosmetic in accordance with Sections 499.06, 499.0632, and 499.065, Florida Statutes, or (iii) seek injunctions and take any other action authorized by Section 499.066 and 499.0661, Florida Statutes, in the event of a public health emergency or any immediate and substantial threat, hazard or danger to public health.

STANDARD PROVISIONS

10. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

11. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2020-011437. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

12. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

13. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

14. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a

single document.

15. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

16. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

17. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this agreement and adopts it in a final order.

18. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

CROWN LABORATORIES, INC.,

By: Jack Songster

Name: JACK SONGSTER

Title: C.O.O.

Date: July 13, 2022

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By:

Name: WALTER COPELAND

Title: DIVISION DIRECTOR

Date: 07.15.2022

Prepared by:

Kathryn E. Rice
DBPR Chief Attorney
Division of Drugs, Devices, and Cosmetics

CROWN
SKIN SCIENCE FOR LIFE

Maine Disciplinary Actions

On July 21, 2021, the Maine Board of Pharmacy fully executed Consent Agreements and Orders for Civil Penalties (referred to as the "Consent Agreements") to resolve *In Matter of: Crown Laboratories, Inc.*, Case No. 2021-PHA-17245 and 17246 before the Maine Board of Pharmacy. In the Consent Agreements, Crown agreed to pay a civil penalty for not reporting the change in ownership within the time frame specified in Maine Board Rules Chapter 12 § 5.

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
CROWN LABORATORIES, INC.	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17245	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Crown Laboratories, Inc. for issuance of a prescription drug manufacturer license. The parties to this Consent Agreement are: Crown Laboratories, Inc. ("Crown"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. From March 10, 2015, to December 31, 2019, Crown was licensed in Maine as a prescription drug manufacturer with a registered location of 349 Lafe Cox Drive, Johnson City, Tennessee (license number **MF30001403**).

2. On December 12, 2017, Crown had a change of ownership.

3. Pursuant to Board Rules Chapter 12 § 5, upon change of ownership of a manufacturer, the manufacturer must file a new application with the Board no less than 7 days prior to the change.

4. Following its change of ownership of the pharmaceutical manufacturing operations, Crown did not file an application with the Board, yet continued to ship prescription drugs to Maine customers.

5. Pursuant to 32 M.R.S. § 13758(2), all manufacturers whose products are distributed in the State in any manner must be licensed by the Board.

6. On March 17, 2020, Crown first submitted an application to the Board to obtain a Maine license to operate as a pharmaceutical manufacturer under the new ownership (pending license number **MF30001816**).

7. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Crown's application to obtain a Maine license to operate as a prescription drug manufacturer. In lieu of the denial, the Board also voted to offer Crown this Consent Agreement. Unless Crown either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, by July 31, 2021, the preliminary denial of Crown's application for licensure as a prescription drug manufacturer will become final.

COVENANTS

8. Crown admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(4) for violating a governing law of the Board, specifically 32 M.R.S. § 13758(2) by repeatedly making

shipments of pharmaceutical drugs into Maine without being properly licensed as a prescription drug manufacturer.

9. As discipline for the violation admitted to in paragraph 8 above, Crown agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of one thousand nine hundred dollars ($1,900.00), which consists $1,500 for engaging in unlicensed practice and $100.00 per shipment of drugs made while not validly licensed, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement;

10. Crown agrees to not ship prescription drugs to Maine unless and until it is licensed by the Board as a prescription drug manufacturer.

11. Violation of any of the terms or conditions of this Consent Agreement by Crown shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

12. The Board and Crown agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Crown fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Crown, and this Consent Agreement will be admitted into

evidence in any future adjudicatory hearing involving Crown. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Crown.

13. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

14. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

15. Upon receipt of the signed Consent Agreement and the civil penalty payment, the Board will issue Crown's license contingent upon it meeting all other eligibility criteria.

16. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

17. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

18. Crown acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 15 July 2021

CROWN LABORATORIES, INC.

By: Marie Fogarile

Print Name: Marie Fogarile

Title: Director, Regulatory Affairs

DATED: 7/16/21

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 7/19/21

JOHN NICHOLS
Assistant Attorney General

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
CROWN LABORATORIES, INC.	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17246	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Crown Laboratories, Inc. for the renewal of its prescription drug manufacturer license. The parties to this Consent Agreement are: Crown Laboratories, Inc. ("Crown"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since March 10, 2015, Crown has been licensed in Maine as a prescription drug manufacturer with a registered location of 349 Lafe Cox Drive, Johnson City, Tennessee, (license number **MF30001403**).

2. On December 12, 2017, Crown had a change of ownership.

3. Pursuant to Board Rules Chapter 12 § 5, upon change of ownership of a manufacturer, the manufacturer must file a new application with the Board no less than 7 days prior to the change.

4. Following its change of ownership of the pharmaceutical manufacturing operations, Crown did not file an application with the Board, yet continued to renew the license and attest the accuracy of the ownership.

5. On November 29, 2018, the Board received Crown's first renewal application since the change of ownership.

6. On that application, Crown responded "No" to the following question: "Has there been a change of ownership of this license since your last renewal?"

7. The Board accordingly renewed Crown's prescription drug manufacturer license.

8. On July 15, 2019, the Alabama State Board of Pharmacy imposed discipline against Crown's Alabama permit (192569) pursuant to a Consent Order in Case No. 18-L-0111.

9. Crown then failed to report this disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

10. On November 6, 2019, Crown reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

11. On November 6, 2019, the Board received Crown's second renewal application since the change of ownership.

12. On that application, Crown responded "No" to the following question: "Has there been a change of ownership of this license since your last renewal?"

13. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

14. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for making a misrepresentation in obtaining a license.

15. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Crown's application for renewal of its license to be a prescription drug manufacturer. In lieu of the denial, the Board also voted to offer Crown this Consent Agreement. Unless Crown either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, by March 12, 2021, the preliminary denial of Crown's application for licensure as a prescription drug manufacturer will become final.

COVENANTS

16. Crown admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. §§ 8003(5-A)(A)(11), and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken;

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its November 29, 2018 application for renewal of licensure; and

c. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its November 6, 2019 application for renewal of licensure.

17. As discipline for the violations admitted to in paragraph 16 above, Crown agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of three thousand five hundred dollars ($3,500.00), which penalty is comprised of $1,500.00 for misrepresentation on its 2018 renewal application, $1,500.00 for misrepresentation on its 2019 renewal application, and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

18. Violation of any of the terms or conditions of this Consent Agreement by Crown shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

19. The Board and Crown agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Crown fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Crown, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Crown. The Board may also consider the

fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Crown.

20. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

21. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

22. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

23. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

24. Crown acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 15 July 2021

CROWN LABORATORIES, INC.

By: Marie Fagarie

Print Name: Marie Fagarie

Title: Director, Regulatory Affairs

DATED: 7/16/21

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 7/19/21

JOHN NICHOLS
Assistant Attorney General

CROWN

SKIN SCIENCE FOR LIFE

Missouri Revoked License

On March 04, 2022, Crown's Missouri Drug Distributor Registrant License was revoked due to an issue with the Missouri Department of Revenue and sales tax return filings for the company. The revocation of the license was not due to any illegal distribution activity, nor any quality issues with any drug products. The tax issues have been resolved with the Department of Revenue and a new license has been issued as Crown Laboratories, Inc. is back in good standing with the Missouri Department of Revenue.

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Acting Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0092 6230 75

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

March 2, 2022

Jeffery Bedard, CEO
Crown Laboratories Inc.
349 Lafe Cox Dr.
Johnson City, TN 37604

Dear Mr. Bedard:

The Missouri Department of Revenue has notified this agency that you are not in compliance with section 144.083.2, RSMo, which requires the possession of a retail sales license and a statement from the department of revenue that the licensee owes no tax due under sections 144.010 to 144.510 or sections 143.191 to 143.261.

Your Drug Distributor Registrant license #2013038468 was revoked on 03/04/2022, you must immediately return your Missouri Drug Distributor Registrant license to the Board of Pharmacy office. Until you resolve this issue with the Department of Revenue, you **CANNOT** reapply for a license and you cannot act as a drug distributor or ship legend drug products into Missouri.

This agency **cannot** intervene with the Department of Revenue on your behalf. You must resolve your tax issues directly with the Department of Revenue at (573) 751-7200.

Sincerely,

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

KAG/jb

cc: Seth A. McKee, Manager-in-Charge CERTIFIED MAIL NO. 9314 8699 0430 0092 6231 12

CROWN

SKIN SCIENCE FOR LIFE

New Hampshire Administrative Disciplinary Action

At its April 15, 2020 Meeting, the New Hampshire Board of Pharmacy ("Board") reviewed the change of ownership application submitted by Crown Laboratories, Inc. on March 31, 2020. While reviewing the application, the Board noted that the application included documentation of disciplinary action in Alabama and Arizona from 2019 and 2020. This discipline had not been previously reported to the New Hampshire Board of Pharmacy. Per RSA 318:51-a, V and Ph I 002.12, the Board must be notified within 30-days of any changes, including disciplinary action in other states. Accordingly, the Board sees fit to assess an administrative fine of $150.00. This fine shall be a non-disciplinary, administrative fine.

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Soleno Therapeutics, Inc.

Physical Address: 100 Marine Parkway, Suite 400

City: Redwood City State: CA Zip: 94065

Mailing Address (if different from physical address): 100 Marine Parkway, Suite 400

City: Redwood City State: CA Zip: 94065

Telephone: (650) 213-8444 Website: https://soleno.life/

Name of Designated Representative (DR): Mitchell Nagao

Licensing Company Email: statelicenses@soleno.life DR Email: mnagao@soleno.life

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty pharmacies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Soleno Therapeutics, Inc.

Corporation Name: Soleno Therapeutics, Inc.

Mailing Address: 100 Marine Parkway, Suite 400

City: Redwood City State: CA Zip: 94065

Telephone: (650) 213-8444 Email: statelicenses@soleno.life

Contact Person Name: Mitchell Nagao

Date of SEC Registration: 02/24/2010	SEC Registration Number: 1484565	Stock Exchange Symbol: SLNO

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Soleno Therapeutics, Inc.
Facility Name

Meredith Manning
Print Name of Authorized Person Submitting Application

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

1/7/2025
Date

Board Use Only	Date Received: 1/15/25	Amount: $1000 ch 2965

DESCRIPTION OF OPERATIONS

SolenoTherapeutics, Inc. ("Soleno") is a publicly held, California-based, clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases.

THIRD-PARTY LOGISTICS

Soleno's products are manufactured by a contract manufacturer and distributed to customers by their third-party logistics provider. Soleno utilizes the following facility for distribution of product:

Biocare Inc. (dba Logicare)
6356 Commercial Drive, Suite 150
Olive Branch, MS 38654
662-782-5278
Scott.garrett@biocaresd.com

CONTRACT MANUFACTURERS

Soleno uses the following contract manufacturer to produce product:

Catalent Inc.
1240 Sugg Parkway
Greenville, NC 27834
252-707-6310
FEIN: 3000209735

PRODUCTS

As a virtual manufacturer, Soleno does not manufacture, distribute or store product at their California facility. At no time do contact manufacturers own Soleno's products, contract with Soleno's customers, invoice or sell Soleno products. Soleno's products are not controlled substances. Accordingly, Soleno is not required to maintain DEA registration.

From: Patricia Hirano
To: Annie Graves
Cc: Jim Mackaness
Subject: FW: Labeler Code Request Approved
Date: Tuesday, April 9, 2024 4:14:16 PM

Hi Annie,

Our Labeler Code is: **83860** and is associated with our DUNS / Soleno Therapeutics Inc.

Best,
Patricia

From: Charles Horn <chorn@soleno.life>
Sent: Friday, December 8, 2023 7:24 AM
To: Patricia Hirano <patricia@soleno.life>
Subject: FW: Labeler Code Request Approved

Hi Patricia,

Don from the FDA called before assigning this morning and said he found the study and would assign it now. He clarified that it would be inactivated in two years if not used. He also said that there are a few administrative things that need to be completed with the application (see below).

Charles

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, December 8, 2023 7:17 AM
To: Charles Horn <chorn@soleno.life>
Subject: Labeler Code Request Approved

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 08-DEC-2023
Labeler DUNS: 088959107
Labeler Name: Soleno Therapeutics Inc.
Labeler Code Assigned: 83860

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to**

complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Company Information

Soleno Therapeutics, Inc.
100 Marine Parkway, Suite 400, Redwood City, CA 94065
(408) 398-1335
www.soleno.life
Email: statelicenses@soleno.life
FEIN: 77-0523891
State of Formation: DE
Date Incorporated: 8/25/1999

Ownership Information

Soleno Therapeutics, Inc. is a publicly traded virtual manufacturing biopharmaceutical company on the NASDAQ stock exchange under the symbol SLNO.

Officers

Anish Bhatnagar, Chief Executive Officer
100 Marine Parkway, Suite 400, Redwood City, CA 94065
Phone: (408) 398-1335

Jim Mackaness, Chief Financial Officer
100 Marine Parkway, Suite 400, Redwood City, CA 94065
Phone: (408) 398-1335

Meredith Manning, Chief Commercial Officer
100 Marine Parkway, Suite 400, Redwood City, CA 94065
Phone: (408) 398-1335

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SOLENO THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3083882 8300

SR# 20250111294

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

Authentication: 202680350

Date: 01-13-25

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8518

ISSUE DATE 11/21/2024

SOLENO THERAPEUTICS INC
100 MARINE PARKWAY SUITE 400
REDWOOD CITY, CA 94065

The above is licensed with the State Board of Pharmacy as a Corporation

NAGAO MITCHELL YUTAKA — EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 11/1/2025

RECEIPT NUMBER 00772077

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

OPHWS1 09/30/19 WLS

Employee	Work location - State
Diana Angelini	California
Marina San Miguel	California
Leo Grace Cahigas	California
Jim Mackaness	California
Berna Demiray	California
Patricia Hirano	California
Michelle Leister	California
Sharon Casey	California
Mung Bernardo	California
Gavin Hettick	California
Leah Pachkowski	California
Alice Li	California
Geeta Dalal	California
Marielle Coleman	California
Erin Bongolan	California
Olivia Wolf	California
Andrea Santa	California
Kristen Yen	California
Meredith Manning	California
Sheri Leung	California
Mitch Nagao	California
Joy Lee	California
Sarah Juhn	California
Raj Gandhi	California
Jina Lee	California
Kristin McCormick	California
Patrick Swan	California
Rachna Desai	California
Carrie Le	California
Alexandra McNely	California
Ceaundra Thomas	California
Kaitlyn Johnson	California
Annie Graves	California
Nick Cali	California
Virginia Wanger	California
Michael Starrett	California
Scott Madsen	California
Andrea Pontis	California
Lauren Budesheim	California
Kathleen Balestra	California
Manolo Lobo	California
Karen Choy	California
Ryan Cavicchi	California
Grace Luk	California

Tom Faucette	California
Kavita Kajla	California
Prateek Banga	California
Rajinder Bahia	California
Sherry Li	California
Ne Lin	California
Svetlana Velkovska	California
Rajashree Sathyamurthy	California
Niki Massoudi	California
Angelina Augustine	California
Anirudh Narula	California
Chen Yu	California
Sydney D'Onofrio	California
Pinar Aycan	California
Josh Caulfield	California
Anish Bhatnagar	California

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2023

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File No.: 001-36593

Soleno Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	77-0523891
(State or other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
203 Redwood Shores Parkway, Suite 500 Redwood City, California	94065
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (650) 213-8444

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SLNO	NASDAQ

Securities Registered Pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of stock held by non-affiliates of the registrant on June 30, 2023, based on the closing price of $4.29 for shares of the registrant's common stock as reported by the Nasdaq Capital Market, was approximately $33.1 million. Shares of Common Stock held by each executive officer, director and beneficial holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates.

As of March 1, 2024, there were 32,460,579 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2024 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2023. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Auditor Name: Marcum LLP Auditor Location: San Francisco, CA Auditor Firm ID: 688

Soleno Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2023

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, particularly in Part I, Item 1: "Business," Part I, Item 1A: "Risk Factors" and Part 2, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," "plan" or "continue," and similar expressions or variations. All statements other than statements of historical fact could be deemed forward-looking, including, but not limited to: any statements regarding the timing of any regulatory process or ultimate approvals and determining a path forward for DCCR (Diazoxide Choline) Extended-Release tablets for the treatment of Prader-Willi syndrome; any projections of financial information; any statements about historical results that may suggest trends for our business; any statements of the plans, strategies, and objectives of management for future operations; any statements of expectation or belief regarding future events, technology developments, our products, product sales, expenses, liquidity, cash flow, market growth rates or enforceability of our intellectual property rights and related litigation expenses; and any statements of assumptions underlying any of the foregoing. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Accordingly, we caution you not to place undue reliance on these statements. Particular uncertainties that could affect future results include: our ability to achieve or maintain profitability; our ability to obtain substantial additional capital that may be necessary to maintain or expand our business; our ability to maintain internal control over financial reporting; our dependence on, and need to attract and retain, key management and other personnel; our ability to obtain, protect and enforce our intellectual property rights; potential advantages that our competitors and potential competitors may have in securing funding or developing products; business interruptions such as earthquakes and other natural disasters; our ability to comply with laws and regulations; potential product liability claims; and our ability to use our net operating loss carryforwards to offset future taxable income. For a discussion of some of the factors that could cause actual results to differ materially from our forward-looking statements, see the discussion on risk factors that appear in Part I, Item 1A: "Risk Factors" of this Annual Report on Form 10-K and other risks and uncertainties detailed in this and our other reports and filings with the Securities and Exchange Commission, or SEC. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

Company Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate, DCCR (Diazoxide Choline) Extended-Release tablets, is a potent ATP-sensitive potassium (K_{ATP}) channel activator. The K_{ATP} channel plays a central role in the regulation of a number of physiological processes which may otherwise be dysregulated, contributing to the pathophysiology of several diseases. In the context of the underlying genetic or structural defects in many forms of hyperphagic obesity, including Prader-Willi syndrome (PWS), these pathophysiological processes may cumulatively contribute to increases in appetite and aggressive food seeking, lack of satiety, accumulation of excess body fat and the establishment and perpetuation of the obese state.

DCCR's unique mode of action with targets in the brain, pancreas and fat tissue has the potential to broadly impact complex diseases like PWS to reduce appetite, reduce food seeking, improve satiety, improve insulin and leptin resistance and reduce body fat. It appears that many of the problematic behaviors in conditions like PWS may have hyperphagic drive as a root cause and may therefore be improved by addressing hyperphagia. We have a Fast-Track designation for DCCR in PWS and orphan designation for the drug in the United States (U.S.) and European Union (E.U.).

DCCR has been evaluated in a Phase 3 study (C601 or DESTINY PWS), a 13-week randomized, double-blind placebo-controlled study, which completed enrollment in January 2020, with 127 randomized participants at 29 sites in the U.S. and United Kingdom (U.K.). Participants who completed DESTINY PWS and sought continued treatment with DCCR were eligible to receive DCCR in a long-term open-label safety extension study (C602). Top line results from DESTINY PWS were announced in June 2020. Although the trial did not meet its primary endpoint of change from baseline in hyperphagia, significant improvements were observed in two of three key secondary endpoints.

In February 2021, we announced analysis limited to data collected before the onset of the COVID-19 pandemic. The analysis of the data through March 1, 2020 showed statistical significance in the primary, all key secondary and several other efficacy endpoints. In September 2021, we announced interim one-year data from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to natural history of PWS from the PATH for PWS Study (PATH) over a one-year treatment period. The PATH study is an ongoing study sponsored by the Foundation for Prader-Willi Research (FPWR) to advance the understanding of the natural history in individuals with PWS.

The U.S. Food and Drug Administration (FDA) provided official meeting minutes from a Type C meeting in January 2022 that recommended additional controlled data be included in a New Drug Approval (NDA) submission.

In March 2022, we submitted an amended protocol that incorporated a randomized withdrawal (RW) period to Study C602 to obtain additional controlled data requested by the FDA and the FDA has acknowledged that data from the study has the potential to support an NDA submission for DCCR. The RW period of Study C602 was a multi-center, randomized, double-blind, placebo-controlled study of DCCR in 77 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. This RW period consisted only of patients previously enrolled in Study C602 and did not enroll any new patients. We announced the initiation of the RW period for Study C602 in October 2022, and completed enrollment in May 2023.

On September 26, 2023, we announced positive statistically significant top-line results from the RW period of Study C602. Subsequently, we received preliminary comments from the FDA for our pre-NDA meeting, and as we decided not to proceed with the meeting, they are considered the official record of the meeting. The FDA stated that the potential for data from the DCCR clinical program to provide substantial evidence of effectiveness will be a matter of review following the submission of an NDA. We plan to submit our NDA for DCCR to the FDA in mid-2024.

Our current focus is the development of DCCR for PWS. However, other syndromes that may be similarly addressed include SH2B1 deficient obesity, Fragile X Prader-Willi Phenotype, KSR2 deficient obesity and other hyperphagic conditions. Another type of disease where DCCR may be efficacious is where hypoglycemia due to excess insulin secretion is a significant problem. Examples include hyperinsulinemic hypoglycemia and certain

Glycogen Storage Diseases. We have orphan drug designation for the treatment of Glycogen Storage Disease Type 1a in the U.S.

Diazoxide Choline Extended-Release Tablets

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly converted to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through K_{ATP} channels and appears to act on signs and symptoms of PWS in a variety of ways. Activating the K_{ATP} channel in NPY/AgRP neurons in the hypothalamus may reduce secretion of neuropeptide Y (NPY), Agouti-related peptile (AgRP) and likely gamma-amino butyric acid (GABA) contributing to a reduction in hyperphagia. Activating the K_{ATP} channel in the dorsal motor nucleus of vagus may potentiate the effects of leptin, insulin and -melanocortin stimulating hormone to reduce hyperinsulinemia and impact appetite and satiety. Activating the K_{ATP} in pancreatic ß-cells can reduce the secretion of insulin, and further reduce the accumulation of excess body fat and the progression to insulin resistance. Activating the K_{ATP} channel in adipocytes has the potential to decrease de-novo triglyceride synthesis and increase ß-oxidation of fat, reducing fat mass.

In the U.S., diazoxide was first approved in 1973 as an intravenous formulation for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations including Proglycem® Oral Suspension and Capsules, or Proglycem, were approved, and there has been nearly 40 years of use of the 2-3 times a day, orally-administered drug product in the approved ultra-rare indications related to hyperinsulinism. Both the capsule and IV formulations have been withdrawn from the U.S. market for reasons other than safety. There is extensive data on short term and chronic use of Proglycem in children with congenital hyperinsulinism, or CHI, and in adults with insulinoma. Insulinoma patients tend to be older, with 50% of them over 70 years old. Published data have reported that the average duration of use of Proglycem in certain CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of dosing required by current diazoxide formulations. Diazoxide choline is formulated into an extended-release tablet that provides lower peak plasma concentration compared to diazoxide oral suspension and allows for the gradual release of diazoxide choline from DCCR, making it suitable for once-a-day dosing. The gradual release and absorption of diazoxide achieved using DCCR results in consistent intraday circulating drug levels potentially reducing the adverse events often associated with transiently high circulating drug levels and providing efficacy at lower diazoxide-equivalent doses.

Prader-Willi Syndrome (PWS)

PWS is a rare, complex neurobehavioral/metabolic disorder caused by the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 60-65% of the cases due to a de novo deletion in the paternally inherited chromosome 15 11-q13 region, 30-35% from maternal uniparental disomy 15, or UPD, where the affected individual inherited 2 copies of the chromosome from their mother and no copy from their father, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e., imprinting defects; IDs). The Committee on Genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 live births. The mortality rate among PWS patients is 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months—67 years).

In addition to hyperphagia, typical behavioral disturbances associated with PWS include skin picking, difficulty with change in routine, obsessive and compulsive behaviors, anxiety and mood fluctuations. The majority of older adolescent and adult PWS patients display some degree of aggressive or threatening behaviors including being verbally aggressive, seeking to intimidate others, being physically aggressive including attacking others, destroying property, throwing temper tantrums and directing rage or anger at others.

PWS is typically thought of as a genetic obesity. However, many PWS patients today may not be obese because of increasing awareness among families and caregivers leading to significant control of access to food and its intake. However, patients remain hyperphagic and will typically have a higher body fat and lower lean body

mass content compared to similarly obese individuals. They are prone to cardiometabolic issues such as abnormal lipid profiles, diabetes and hypertension associated with obesity once it is established. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, insistence on sameness, and their association with maladaptive conduct problems. Cognitively, most individuals with PWS function in the mild intellectual disability range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors make it difficult for individuals with PWS to perform to their IQ potential. Some older adolescents and many adults reach a stage at which they can no longer be effectively managed in the home and therefore transition to institutional care.

Unmet Medical Needs in PWS

The target indication for DCCR is the treatment of PWS. Currently, the only approved treatment related to PWS is growth hormone which addresses the short stature associated with PWS but has no effect on hyperphagia. A global patient survey conducted by the Foundation for Prader-Willi Research (n=779), found that 96.5% of respondents rated reducing hunger and 91.2% rated improving behavior around food as a very important or the most important symptom to be relieved by a new treatment - https://www.fpwr.org/pws-patient-voices. Physical function and body composition symptoms for which a high percentage of respondents indicated were very important or most important included: 92.9% indicated improving metabolic health (reduces fat / increases muscle) and 81.3% indicated the related symptom of improving activity and stamina. The behavioral and cognitive symptoms rated by respondents as very or most important were: 85.2% indicated reduction of obsessive/compulsive behavior, 84.6% indicated improvements to intellect/development, and 83.2% indicated reduction of temper outburst severity and frequency.

Therefore, there is a clear unmet need in the treatment of PWS to reduce hyperphagia and improve behaviors around food, and to reduce other behavioral and cognitive impacts of this complex disease. In addition, improving metabolic health is also an important unmet need.

Clinical Trials of DCCR for PWS

A Phase 2 clinical trial was conducted to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 11 and 21. The first phase of the study was open-label during which subjects were initiated on a DCCR dose that was escalated every 14 days at the discretion of the investigator. Any subject who showed any increase in resting energy expenditure and/or a reduction in hyperphagia from baseline at certain study visits would be designated a responder, whereas all others would be designated non-responders. This 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase.

Responders were randomized in a 1:1 ratio either to continue on active treatment at the dose they were treated with, or to the placebo equivalent of that dose for an additional 4 weeks. Of the 13 subjects who enrolled, 11 completed the open-label phase and all were designated as responders; the remaining two subjects had discontinued prematurely.

Key efficacy results included a statistically significant reduction in hyperphagia from baseline to the end of the open-label treatment phase. In addition, greater improvement in hyperphagia from baseline was observed in those subjects with moderate to severe hyperphagia who received higher DCCR doses. There was a significant improvement in the number of subjects reporting one or more aggressive and destructive behaviors. During the open-label treatment phase, a mean decrease in body fat mass and increases in lean body mass and lean body mass / fat mass ratio were seen. These changes were associated with a statistically significant reduction in waist circumference, consistent with the loss of visceral fat. Statistically significant reductions from baseline in LDL cholesterol and non-HDL cholesterol were observed.

As described above in the Company Overview, a Phase 3 clinical trial, DESTINY PWS, was subsequently conducted to evaluate the efficacy and safety of DCCR in patients with genetically-confirmed PWS. Top-line results were reported in June 2020. Although the trial did not meet its primary endpoint of change from baseline in

hyperphagia, significant improvements were observed in two of three key secondary endpoints. Subjects who complete the DESTINY PWS study were allowed to enroll in a long-term, safety extension study (C602). In September 2021, we announced top-line results from the analysis of one-year data from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to the natural history of PWS from the PATH for PWS Study (PATH) over a one-year treatment period. PATH is an ongoing study sponsored by the Foundation for Prader Willi Research (FPWR) evaluating the natural history of subjects with PWS in more than 700 families. In October 2022 we announced the initiation of the RW period of Study C602, which was a multi-center, randomized, double-blind, placebo-controlled study of DCCR in 77 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. This RW period consisted only of patients previously enrolled in Study C602 and did not enroll any new patients. In May 2023, we completed enrollment and we announced positive statistically significant top-line results from the RW period of Study C602 in September 2023.

Safety of DCCR in the Treatment of PWS

Across the combined C601 (DESTINY-PWS), and C602 long-term open-label extension (OLE) studies (which included DCCR treatment durations of up to ~4.5 years), 98.4% of participants reported treatment emergent adverse events (TEAEs). Most were grade 1 or 2 (75.2%), with no grade 4 or higher events. The most common TEAEs were hypertrichosis (68.8%), peripheral edema (34.4%), hirsutism (27.2%) and hyperglycemia (27.2%).

The majority of participants with hypertrichosis, hirsutism, or hyperglycemia experienced resolution or improvement of their symptoms with continued DCCR dosing through the end of the study. Infrequently, DCCR dose adjustments or glucose-lowering agents (for hyperglycemia) and diuretics (for peripheral edema) were prescribed to manage participants experiencing these TEAEs.

One participant with a known history of psychiatric illness reported a suspected unexpected serious adverse reaction (SUSAR) of aggression in the ongoing C614 open label extension study.

Overall, the safety profile of DCCR in the Phase 3 PWS clinical development program was generally consistent with the known safety profile of diazoxide and prior experience with DCCR.

Regulatory Status of DCCR for the Treatment of PWS

Diazoxide choline is being developed in the U.S. under a current Investigational New Drug Application (IND) and is designated as an Orphan Drug for the treatment of PWS in the U.S. and Europe and granted Fast Track designation in the U.S. If certain criteria are met, DCCR may be eligible for "Accelerated Approval" and "Priority Review" and also "Rolling Review", which would allow us to submit to the FDA sections of our NDA as they are finished instead of waiting for all sections to be completed before submitting the marketing application. The current status of our Phase 3 clinical trial is described above in the Company Overview.

Market opportunity

An estimated 300,000 to 400,000 individuals worldwide have PWS with a birth incidence ranging from 1:15,000 to 1:25,000. In addition, according to an abstract published in the Journal of Endocrine Society, a 2020 review of medical claims provided by IQVIA Health Plan and CMS Medicare fee-for-service claim data, demonstrated a U.S. diagnosed PWS prevalence of approximately 9,000 patients in the United States in 2018. The numbers of identified PWS patients is growing at a rate that is higher than the rate of general population because of improved rates of diagnosis. DCCR may be the first effective treatment for hyperphagia in PWS patients to reach the market both in the U.S. and Europe and may therefore be likely to be used in a large proportion of patients.

Sales and Marketing

Newly diagnosed PWS patients are typically treated by a multi-disciplinary team led by a pediatric endocrinologist. Many patients receive care at larger clinics devoted to PWS in university-associated hospitals or at children's hospitals. This concentration of care may allow us to market DCCR without a partner by assembling a small, dedicated salesforce to target the limited number of major PWS treatment centers in the U.S. We believe

similar dynamics exist in Europe. In contrast, we will likely need to identify a marketing partner for DCCR in Japan, and the rest of the world. The final decision on sales and marketing strategy will be made at a later date.

Pricing

We have not conducted a formal pricing analysis of DCCR in PWS. We anticipate that pricing at launch may be influenced by the product label negotiated with the FDA, pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

Competition

Currently, the only approved products for PWS are Genotropin® (somatropin), and Omnitrope® (somatropin) which are approved only for growth failure due to PWS. There are no approved products to address PWS-associated hyperphagia and behaviors, or for any other abnormalities associated with the disease. However, to our knowledge, there are a number of therapeutic products at various stages of clinical development for the treatment of PWS, including for hyperphagia, by Acadia Pharmaceuticals, Aardvark Therapeutics, Gedeon Richter, and Consynance.

Manufacturing

Pharmaceuticals

Our manufacturing strategy is to contract with third parties to manufacture our clinical and commercial API and drug product supplies.

The formulation and processes used to manufacture our products are proprietary, being covered by multiple issued U.S. patents and counterparts in other regions of the world, and we have agreements with various third-party manufacturers that are intended to restrict these manufacturers from using or revealing any unpublished proprietary information.

Our third-party manufacturers and corporate partners are independent entities who are subject to their own operational and financial risks over which we have no control. If we or any of these third-party manufacturers fail to perform as required, this could cause delays in our clinical trials and regulatory applications and submission.

Regulation of Pharmaceutical Manufacturing Processes

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations, legislations, and/or guidelines. We and our third-party manufacturers are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping, and quality standards as defined by the FDA and the EMA. Similar regulations and requirements are in effect in other countries.

Intellectual Property

DCCR Patent Portfolio

Our patent portfolio consists of issued U.S. patents and pending U.S. applications. The 20-year expiration dates of our issued U.S. patents are between 2025 to 2035. We also have issued patents in Europe, Canada, Japan, China, India, Israel, Hong Kong, Australia, Malaysia, Mexico, New Zealand, Singapore, Indonesia, Korea, and Eurasia. We are prosecuting numerous patent applications in major pharmaceutical markets around the world. The issued patents and pending patent applications include protection of compositions, methods of manufacturing, pharmaceutical formulations, and methods of treating aspects of PWS and Smith-Magenis syndrome (SMS).

Government Regulation - Pharmaceuticals

Our operations and activities are subject to extensive regulation by government authorities in the U.S. and in other countries in which we elect to develop and/or commercialize our products. Our developmental drug products are subject to rigorous regulation. Federal and state statutes and regulations govern the testing, manufacture, safety,

efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming.

A country's regulatory agency, such as the FDA in the U.S., or a region's agency, such as the EMA for the E.U., must approve a drug before it can be sold in the respective country or countries. The general process for drug approval in the U.S. is summarized below. Many other countries, including countries in the E.U., U.K. and Japan, have very similar regulatory approval processes.

Nonclinical Testing

Before a drug candidate can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and/or safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogenicity studies in two species are generally required for products intended for long-term use.

Investigational New Drug Exemption Application (IND)

The results of initial nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. If the FDA does not identify significant issues during the initial 30-day IND review, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. Each clinical trial protocol and/or amendment, new nonclinical data, and/or new or revised manufacturing information must be submitted to the IND, and the FDA has 30 days to complete its review of each submission.

Clinical Trials

These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

Phase 1 Studies. During Phase 1 studies, researchers test a new drug in healthy volunteers. In most cases, 20 to 80 healthy volunteers participate in Phase 1. Phase 1 studies are closely monitored and gather information about how a drug interacts with the human body. Researchers adjust dosing schemes based on animal data to find out how much of a drug the body can tolerate and what its acute side effects are. As a Phase 1 trial continues, researchers answer research questions related to how it works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits. This is important to the design of Phase 2 studies.

Phase 2 Studies. In Phase 2 studies, researchers administer the drug to a group of people with the disease or condition for which the drug is being developed. Typically involving up to a few hundred patients, these studies are not large enough to show whether the drug will be beneficial. The use of new study designs, such as adaptive designs, can decrease the number of patients required. Instead, Phase 2 studies provide researchers with additional safety data. Researchers use these data to refine research questions, develop research methods, identify target doses, and design new Phase 3 research protocols.

Phase 3 Studies. Researchers design Phase 3 studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies generally involve a larger number of participants than do Phase 2 studies. Phase 3 studies provide most of the safety data. In Phase 3 studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects.

For each clinical trial, an institutional review board (IRB) or independent ethics committee (IEC), covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and written informed consent or assent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, other heath authority, the IRB/IEC, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB/IEC's requirements, or may impose other conditions.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with good clinical practices (GCP) requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

FDA Approval Process

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we would intend to submit an application to market the drug for a particular use, an NDA or BLA with the FDA. The FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes recommendations to the FDA that are not binding but are generally followed by the FDA. If the FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow the drug product to be marketed in the U.S. and sold for that use. It is not unusual, however, for the FDA to reject an application because it believes that the risks of the drug candidate outweigh the purported benefit or because it does not believe that the data submitted are reliable or conclusive. The FDA may also issue a Complete Response Letter (CRL), to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. The FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. The FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for our drug, the manufacturing facilities of the companies who manufacture our drugs for us must also be approved. These facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the U.S. and these facilities are subject to periodic regulatory inspection.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track and/or breakthrough candidates by the FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases (i.e., in the U.S., the disease or condition has a prevalence of less than 200,000 persons; in the E.U., the prevalence of the condition must be not more than 5 in 10,000) can be designated as "Orphan Drugs". In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions and administrative actions will impact the scope of the orphan drug exclusivity. In the E.U., products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

Ongoing Regulation

Once a pharmaceutical product is approved, a product will be subject to pervasive and continuing regulation by the FDA, EMA, and other health authorities, including, among other things, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. The Federal Trade Commission (FTC) also regulates the promotion and advertising of consumer products. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. Manufacturers may not promote a drug that is still under development and has not been approved by the FDA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Drugs are also subject to extensive regulation outside of the U.S. In the E.U., there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. through a single application and review process. If this centralized approval procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the E.U. registration procedures, separate pricing and reimbursement approvals are also required in most countries. The E.U. also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Additional Government Regulations

HIPAA and Other Privacy Laws

HIPAA, established for the first-time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Covered Entities and their Business Associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are presently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, HITECH and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. Most of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We may perform future activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue samples and associated patient information could significantly impact our business and our future business plans.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state antifraud and abuse laws. Many of these antifraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

- the submission, or causing the submission of, false claims or false information to government programs;
- deceptive or fraudulent conduct;
- performing medically unnecessary procedures; and
- prohibitions in defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment and refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil monetary and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud. The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, violations of the federal physician self-referral laws, such as the Stark laws discussed below, may also violate false claims laws. Liability under the False Claims Act can result in treble damages and imposition of penalties. For example, we could be subject to penalties of $13,508 to $27,018 per false claim, adjusted each year for inflation, and each use of our product could potentially be part of a different claim submitted to the government. Separately, the HHS office of the Office of Inspector General, or OIG, can exclude providers found liable under the False Claims Act from participating in federally funded healthcare programs, including Medicare and Medicaid. The steep penalties that may be imposed on laboratories and other providers under this statute may be disproportionate to the relatively small dollar amounts of the claims made by these providers for reimbursement. In addition, even the threat of being excluded from participation in federal healthcare programs can have significant financial consequences on a provider.

Numerous federal and state agencies enforce the antifraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

Federal and State "Self-Referral" and "Anti-Kickback" Restrictions

Self-Referral law. We are subject to a federal "self-referral" law, commonly referred to as the "Stark" law, which provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals.

We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law. For example, we are subject to a North Carolina self-referral law that prohibits a physician investor from referring to us any patients covered by private, employer-funded or state and federal employee health plans. The North Carolina self-referral law contains few exceptions for physician investors in securities that have not been acquired through public trading but will generally permit us to accept referrals from physician investors who buy their shares in the public market.

We have several stockholders who are physicians in a position to make referrals to us. We have included within our compliance plan procedures to identify requests for testing services from physician investors and we do not bill Medicare, or any other federal program, or seek reimbursement from other third-party payors, for these tests.

Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment and refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties, and they may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of $13,508 to $27,018 for each separate false claim. Similarly, sanctions for violations under the North Carolina self-referral laws include refunds and monetary penalties.

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010 (PPACA), which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties and exclusion from participation in federal healthcare programs.

The OIG has criticized a number of the business practices in the clinical laboratory industry as potentially implicating the Anti-Kickback Statute, including compensation arrangements intended to induce referrals between laboratories and entities from which they receive, or to which they make, referrals. In addition, the OIG has indicated that "dual charge" billing practices that are intended to induce the referral of patients reimbursed by federal healthcare programs may violate the Anti-Kickback Statute.

Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. For example, North Carolina has an anti-kickback statute that prohibits healthcare providers from paying any financial compensation for recommending or securing patient referrals. Penalties for violations of this statute include license suspension or revocation or other disciplinary action. Other states have similar anti-kickback prohibitions.

Both the federal Anti-Kickback Statute and the North Carolina anti-kickback law are broad in scope. The anti-kickback laws clearly prohibit payments for patient referrals. Under a broad interpretation, these laws could also prohibit a broad array of practices involving remuneration where one party is a potential source of referrals for the other.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country in the future, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance plan. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the

operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Other Corporate Transactions

Underwritten Public Offerings and Concurrent Private Placement

On March 31, 2022, we sold 2,666,666 shares of our common stock at a public offering price of $3.75 per share and, for certain investors, in lieu of common stock, pre-funded warrants to purchase 1,333,333 shares of our common stock at a public offering price of $3.60 per pre-funded warrant, which represents the per share public offering price for the common stock less the $0.15 per share exercise price for each pre-funded warrant. Each share of common stock or pre-funded warrant was sold together with one, immediately exercisable, common warrant with a five-year term to purchase one share of common stock at an exercise price of $4.50 per share. The net proceeds of the offering were $13.8 million, after deducting the underwriting discount and other offering expenses.

On October 2, 2023, we announced the closing of the underwritten public offering of 3,450,000 shares of our common stock at a public offering of $20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $69.0 million, before deducting the underwriting discount and other estimated offering expenses. We also announced the closing of approximately $60.0 million of shares of our common stock and pre-funded warrants in a concurrent private offering pursuant to a securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of $20.00 and a price per per-funded warrant of $19.99. In aggregate, we received $129.0 million of gross proceeds from the underwritten public offering and concurrent private placement.

Securities Purchase Agreement

In December 2022, we entered into a securities purchase agreement providing for the sale of up to $60.0 million in warrants (divided into two tranches, Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. We issued both tranches of warrants in exchange for an aggregate purchase price of $10.0 million in May 2023. The announcement of positive top-line data from the randomized withdrawal period of Study C602 in September 2023 triggered the mandatory exercise of the Tranche A warrants, and we received $15.0 million in gross proceeds. Between October 2023 and the end of 2023, several investors exercised their Tranche B warrants and we received $18.1 million in gross proceeds. The remaining Tranche B warrants may be exercised for an additional $16.9 million in proceeds to us.

At the Market Offering

In 2022, we sold 104,773 shares of common stock and raised $0.3 million in net proceeds, and in 2023, we sold 1,772,397 shares of common stock and raised $7.1 million in net proceeds pursuant to a Controlled Equity Offering Sales Agreement under which we could sell shares of our common stock having an aggregate offering price of up to $25.0 million from time to time in any method permit by law deemed to be an "at the market" Rule 415 under the Securities Act of 1933, as amended. The Controlled Equity Offering Sales Agreement was terminated in connection with the October 2, 2023 financing.

4L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01152	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Kuehne + Nagel Inc.

Physical Address: 1800 Waters Ridge Dr, Suite 100

City: Lewisville State: TX Zip: 75057

Mailing Address (if different from physical address): 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 972-459-7635 Website: https://us.kuehne-nagel.com/

Name of Designated Representative (DR): Sharon McCabe

Licensing Company Email: qshepharma.us@kuehne-nagel.com DR Email: sharon.mccabe@kuehne-nagel.

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3rd Party Logistics Provider

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/18/2024

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: AbbVie, Inc.
Address: 1 North Waukegan Road City: North Chicago State: IL Zip: 60065
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): Kuehne + Nagel Holdings Inc.
Corporation/Organization Name: Kuehne + Nagel Inc.
Mailing Address: 10 Exchange Place 20th Floor
City: Jersey City State: NJ Zip: 07302
Telephone: 201-413-5500 Email: qshepharma.us@kuehne-nagel.com
Contact Person Name: Natalie Martino

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kuehne + Nagel Inc.

Facility Name

Dan Osterberg

Print Name of Authorized Person Submitting Application

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

11/18/2024

Date

Board Use Only	Date Received: 12/5/24	Amount: $1000-CK 13447

NABP ACCREDITED
DRUG DISTRIBUTOR

Kuehne + Nagel, Inc

located at

1800 Waters Ridge Dr, Lewisville, TX 75057

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/30/2022 - 12/29/2025
Period of Accreditation

NABP ACCREDITED
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1800 Waters Ridge Dr, Lewisville, TX 75057

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Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/30/2022 - 12/29/2025
Period of Accreditation

KUEHNE+NAGEL

Owner:
Kuehne + Nagel Investment, LLC
10 Exchange Place 19th floor, Jersey City NJ 07302
FEIN: 22-3176791
100% Ownership

List of Officers:

Marcus Bennett, President/CEO

[redacted]

Dan Osterberg, CFO

[redacted]

Richard J Kaluzinski, Secretary, National Legal Counsel

[redacted]

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	KUEHNE + NAGEL INC.
DOS ID Number:	200052
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/30/1966
Effective Date:	05/01/2023
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 16, 2024 at 04:29 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006589450 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

TEXAS Department of State Health Services

License Number: 1000482 ***Current Date: 09/16/2024 02:35 PM***

Name:	KUEHNE + NAGEL INC
License Type:	Prescription Drug Distributor
License Status:	Current
Expiry Date:	10/03/2026
Effective Rank Date:	10/18/2010
Modifier(s):	Prescription
	Non Prescript
	Veterinary
	Third Party Logistics Provider

Addresses

Mailing Address	Address	KUEHNE + NAGEL INC ATTN COMPLIANCE JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302
Physical Loc	Address	KUEHNE + NAGEL INC 1800 WATERS RIDGE DR STE 100 LEWISVILLE , TX DENTON 75057 US

Food & Drug Owner

Licensee's Role:	Food & Drug License
Related Party Role:	Food & Drug Owner

Related Party Name	License	Address
KUEHNE + NAGEL INC	Owner #A036489 Status: Current Expiration Date:	JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302 US

License Number: 1000482 ***Current Date: 03/19/2025 10:24 AM***

Name:	**KUEHNE + NAGEL INC**
License Type:	**Prescription Drug Distributor**
License Status:	**Current**
Expiry Date:	**10/03/2026**
Effective Rank Date:	**10/18/2010**
Modifier(s):	**Prescription**
	Non Prescript
	Veterinary
	Third Party Logistics Provider

Addresses

Physical Loc	Address	KUEHNE + NAGEL INC 1800 WATERS RIDGE DR STE 100 LEWISVILLE , TX DENTON 75057 US
Mailing Address	Address	ATTN HEALTHCARE REGULATORY JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
KUEHNE + NAGEL INC	**Owner #A036489** Status: Current Expiration Date:	JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302 US

List of Licenses-LIV

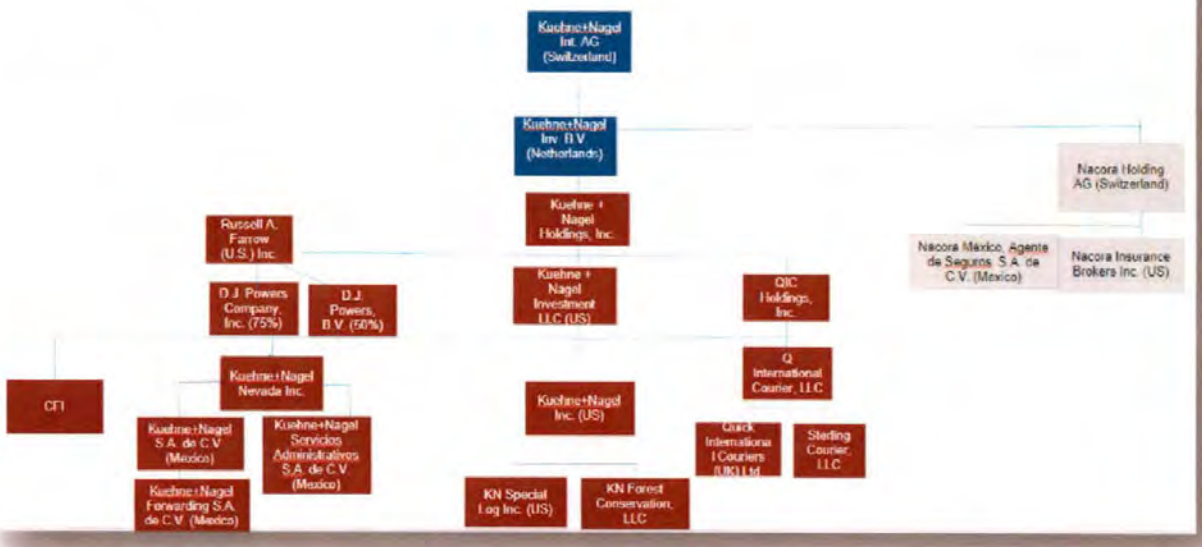
Jurisdiction	Requirement	Number	Issue Date	Expiration Date
US-AL	Third Party Logistics	192844	11/27/2002	12/31/2024
US-AR	Wholesale Distributor	WD03018	01/03/2005	12/31/2024
US-AZ	Third Party Logistics Provider	L000055	08/31/2017	10/31/2025
US-CA	Non-Resident Third Party Logistics Provider	NPL 1043	08/28/2015	08/01/2025
US-CO	Third Party Logistics Provider	TPLP.0000099	07/23/2024	10/31/2026
US-CT	Wholesaler of Drugs, Cosmetics & Medical Devices	CSW.0002832	07/01/2024	06/30/2025
US-DE	Pharmacy - Wholesale	A4-0001778	02/14/2011	09/30/2026
US-FL	Complimentary Drug Distributor	40547	10/20/2011	10/31/2025
US-FL	Third Party Logistics Provider	02103	10/20/2011	10/31/2025
US-GA	Wholesaler Pharmacy	PHWH003610	02/17/2014	06/30/2025
US-IA	Limited Distributor/Medical Gas Distributor	40968	10/01/2019	12/31/2024
US-IA	Third Party Logistics Provider	80038	04/03/2019	03/31/2025
US-IL	Third Party Logistics Provider	278000092	08/09/2021	12/31/2024
US-IN	Third Party Logistics Provider	94000275A	02/12/2024	09/30/2026
US-KS	Third-Party Logistics Provider	23-30836	06/25/2020	06/30/2025
US-KS	Sample Distributor	15-112521	08/03/2020	06/30/2025
US-KY	Third Party Logistics Provider	TPL00142	08/31/2017	06/30/2025
US-LA	Third Party Logistics Provider	5963	06/01/2008	12/30/2024
US-MI	Manufacturer	5306003964	10/16/2012	10/16/2025
US-MO	Third Party Logistics Provider	2012040604	12/03/2012	10/31/2025
US-MS	Third Party Logistics Provider	16168	07/14/2017	12/31/2024
US-MT	Wholesale Drug Distributor	PHA-WDD-LIC-14868	02/06/2013	11/30/2025
US-NC	Third Party Logistic Provider	985	12/08/2023	12/31/2024
US-ND	Third Party Logistics Provider	TPL1242	05/23/2013	06/30/2025
US-NH	Manufacturer / Distributor / Wholesaler / Broker	06916	05/18/2020	06/30/2026
US-NM	Third Party Logistics Provider	WD00011693	10/17/2013	12/31/2025
US-NV	Wholesaler	WH01152	04/25/2003	10/31/2026
US-OH	Third-Party Logistics - Category 2	012252050	10/10/2012	06/30/2025
US-OK	Third Party Logistics Provider	88-L-8551	06/03/2024	06/30/2025
US-OR	Drug Distribution Agent	DDA-0000120	10/01/2015	09/30/2025
US-PA	Distributor of Prescription Drugs	3000008923	07/24/2012	10/31/2025
US-SC	Non-Resident Third Party Logistics Provider	14979	12/13/2013	06/30/2025
US-TN	Third Party Logistics Provider	00003996	08/16/2013	08/31/2025
US-TX	Device Manufacturer	1002134	04/11/2018	03/05/2026
US-TX	Multiple Products with Non-Prescription Drugs	0073597	03/24/2004	12/31/2024
US-TX	Prescription Drug Distributor	1000482	10/18/2010	10/03/2026
US-UT	Pharmacy - Class C	9126818-1710	08/18/2014	09/30/2025
US-VA	Non-Resident Third Party Logistics Provider	0242000058	07/01/2019	02/28/2025
US-VT	Third Party Logistics Provider	159.0000075	07/31/2019	07/31/2025
US-WA	Drug Sample Distributor Registration	DRSD.FX.60188828		09/30/2025
US-WI	Wholesale Distributor of Prescription Drugs	2519-45	02/13/2013	05/30/2026
US-WV	Third Party Logistics Provider	3PL0000010	06/18/2024	06/30/2026
US-WY	Third Party Logistics Provider	3PL0084	06/18/2024	06/30/2025

KUEHNE+NAGEL

Kuehne+Nagel U.S. Legal Structure

September 1, 2024

KUEHNE+NAGEL



Anticipated Kuehne+Nagel U.S. Legal Structure

December 1, 2024

KUEHNE+NAGEL

Kuehne + Nagel Inc.

10 Exchange Pl
Floor 20
Jersey City, NJ 07302

Tel.: +1 484.995.6137
ria.philip@kuehne-nagel.com

us.kuehne-nagel.com
www.kuehne-nagel.com

AGREEMENT
AND
PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER, dated as of November 11, 2024 (this "Plan of Merger"), is between Kuehne + Nagel Investment LLC, a New Jersey Limited Liability Company ("Merged LLC"), and Kuehne + Nagel Holdings, Inc., a Delaware corporation ("Surviving Corporation").

W I T N E S S E T H:

WHEREAS, Merged LLC has a single member to wit, the Surviving Corporation; and

WHEREAS, Surviving Corporation is authorized to issue a total of 100 shares of capital stock, consisting of 200 shares of common stock, par value $0.01 per share ("Surviving Corporation Common Stock"), of which, as of the date hereof, 100 shares of Common Stock are issued and outstanding; and

WHEREAS, the sole member and the Managers of the Merged LLC and the Board of Directors of the Surviving Corporation, respectively, approve and deem it advisable that Merged LLC and Surviving Corporation, respectively, consummate the Merger (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements contained in this Plan of Merger, the parties to this Plan of Merger hereby agree that Merged LLC shall be merged (the "Merger") with and into Surviving Corporation in accordance with applicable laws and upon the terms and subject to the conditions set forth as follows:

1. The Merger. At such time agreed between Merged LLC and Surviving Corporation, a certificate of merger evidencing the Merger shall be filed with each of the Office of the Secretary of State of the State of New Jersey pursuant to the Title 42 of the New Jersey Revised Statutes and of the State of Delaware General Corporation Law. The Certificates of Merger shall specify that the Merger shall become effective on December 1, 2024 ("Effective Time"). At the Effective Time, Merged LLC shall be merged with and into Surviving Corporation, and Surviving Corporation shall continue as the surviving corporation. The Surviving Corporation's name shall remain Kuehne + Nagel Holdings, Inc.

2. Certificate of Incorporation and By-laws. The Certificate of Incorporation and By-laws of Surviving Corporation in effect immediately prior to the Effective Time shall be and remain the Certificate of Incorporation and By-laws, respectively, of Surviving Corporation, as the surviving corporation, after the Effective Time, until amended as provided by law.

3. Officers and Directors. From and after the Effective Time, and until they shall have resigned or shall have been legally removed or until their respective successors shall have been elected or appointed and qualified, those persons who are the officers and directors of Surviving Corporation immediately prior to the Effective Time shall be the officers and directors of Surviving Corporation.

4. Effect of the Merger.

4.1 All assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC in and to every type of property (real, personal and mixed) and choses in action, as they exist as of the Effective Time, shall pass and be transferred to and vest in Surviving Corporation, as the surviving corporation, by virtue of the Merger at the Effective Time without any deed, conveyance or other transfer, and all such interests of Surviving Corporation as they exist as of the Effective Time shall remain with Surviving Corporation upon consummation of the Merger. The corporate existence of Surviving Corporation shall continue unaffected and unimpaired upon consummation of the Merger and the separate corporate existence of Merged LLC shall cease at and as of the Effective Time.

4.2 From and after the Effective Time, Surviving Corporation, as the surviving corporation, shall be responsible and liable for all of the liabilities and obligations of Surviving Corporation and Merged LLC existing as of the Effective Time. Any claim existing or action or proceeding pending by or against Surviving Corporation or Merged LLC at the Effective Time may, thereafter, be prosecuted by or against Surviving Corporation, as the surviving corporation, as if the Merger had not taken place or, in connection with any such action or proceeding to which Merged LLC is a party, Surviving Corporation, as the surviving corporation, may be substituted in place of Merged LLC. Neither the rights of creditors nor any liens upon the property of either Surviving Corporation or Merged LLC shall be impaired by reason of the Merger.

5. Effect of Merger on Outstanding Shares.

5.1 *Exchange Ratio*. At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof, all of the issued and outstanding member shares of the Merged LLC shall be cancelled.

5.2 *Closing of Transfer Books*. At the Effective Time, the membership transfer books of Merged LLC shall be closed and no transfer of shares of Merged LLC membership shall thereafter be made. If, after the Effective Time, certificates representing member shares of Merged LLC are presented to the Surviving Corporation, they shall be canceled in accordance with the terms hereof. At and after the Effective Time, the holders of member shares of Merged LLC Stock shall cease to have any rights as members of Merged LLC.

6. Further Assurances. From time to time after the Effective Time, as and when requested by Surviving Corporation, and to the extent permitted by law, the former managers of Merged LLC and the officers and directors of Surviving Corporation shall execute and deliver such assignments, deeds and other instruments and shall take or cause to be taken such further or other action as shall be necessary in order to consummate the Merger, vest or perfect in or to confirm of record or otherwise to Surviving Corporation, as the surviving corporation, title to, and possession of, all of the assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC and Surviving Corporation in and to every type of property (real, personal and

mixed) and choses in action, and otherwise to carry out the purposes of this Plan of Merger, and the proper officers and directors of Surviving Corporation, as the surviving corporation, are fully authorized to take any and all such action in the name of Merged LLC or Surviving Corporation or otherwise.

7. Termination and Amendment. Prior to the Effective Time, this Plan of Merger may be terminated or amended by the mutual consent of the Managers of Merged LLC and the Board of Directors of Surviving Corporation.

8. Counterparts. This Plan of Merger may be signed in any number of counterparts, each of which shall be deemed an original, and all of which shall be deemed but one and the same instrument.

9. Governing Law. This Plan of Merger shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New Jersey or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New Jersey.

IN WITNESS WHEREOF, the parties have duly executed this Plan of Merger as of the date first written above.

KUEHNE + NAGEL INVESTMENT LLC
(Merged LLC)

By: _____
Marcus Bennett, Manager

By: _____
Dan Osterberg, Manager

By: _____
Nadine Jones, Manager

KUEHNE + NAGEL HOLDINGS, INC.
(Surviving Corporation)

By: _____
Name: Dan Osterberg
Title: CFO, Treasurer

Lexon Insurance Company

November 20, 2024

Nevada Board of Pharmacy

Bond Name: KUEHNE + NAGEL INC.
Bond Number: 413722
Amount: $100,000.00
Effective Date: 10/31/2006

Rider Executed and Effective November 20, 2024

The above referenced bond includes the following K+N facility location to ensure sufficient coverage:

1025 Columbia Rd, Suite 110, Plainfield, IN 46168

4080 Executive Drive, Suite 100, Southaven, MS 38672

2555 USA Parkway, Suite 104, McCarran, NV 89434

324 Half Acre Road, Cranbury, NJ 08512

2532 Whilden Drive, Durham, NC 27713

6005 Freeport Avenue, Suite 103, Memphis, TN 38141

2600 Regent Blvd Dallas, TX 75261

1800 Waters Ridge Drive, Suite 100, Lewisville, TX 75057

Nothing herein contained shall be held to vary, alter or waive or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond or policy, other than as above stated.

Lexon Insurance Company

James Reiss, Attorney in Fact

By:

NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0413722

Application/License No. WH00941

Kuehne + Nagel Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
6005 Freeport Ave #J-122, Memphis TN 38141, as
Address of Applicant/Principal
PRINCIPAL, and International Fidelity Insurance Co., a
Surety Company
corporation organized under the laws of the state of New Jersey
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Newark Center, Newark NJ 07102 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on _____.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL

_____
Authorized Representative

SURETY COMPANY

International Fidelity Ins. Co.
Surety Company's Representative

Kevin A. Tattam, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Benny Munoz
Witness

Martino Sessa
Witness

Countersigned by:

Nevada Resident Agent

NEVADA BONDING AGENCY, INC.
P.O. BOX 80987
LAS VEGAS, NV 89180
PHONE (702) 631-0878
FAX (702) 647-5391

POWER OF ATTORNEY

LX - 015431

Lexon Insurance Company

KNOW ALL MEN BY THESE PRESENTS, that **LEXON INSURANCE COMPANY**, a Texas Corporation, with its principal office in Louisville, Kentucky, does hereby constitute and appoint: Kevin Tattam **********

****

its true and lawful Attorney(s)-In-Fact to make, execute, seal and deliver for, and on its behalf as surety, any and all bonds, undertakings or other writings obligatory in nature of a bond.

This authority is made under and by the authority of a resolution which was passed by the Board of Directors of **LEXON INSURANCE COMPANY** on the 1st day of July, 2003 as follows:

Resolved, that the President of the Company is hereby authorized to appoint and empower any representative of the Company or other person or persons as Attorney-In-Fact to execute on behalf of the Company any bonds, undertakings, policies, contracts of indemnity or other writings obligatory in nature of a bond not to exceed $ 7,100,000.00 Seven million one hundred thousand dollars ********** dollars, which the Company might execute through its duly elected officers, and affix the seal of the Company thereto. Any said execution of such documents by an Attorney-In-Fact shall be as binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company. Any Attorney-In-Fact, so appointed, may be removed for good cause and the authority so granted may be revoked as specified in the Power of Attorney.

Resolved, that the signature of the President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Vice President, and the seal of the Company may be affixed by facsimile to any certificate of any such power and any such power or certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certificate so executed and sealed shall, with respect to any bond of undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS THEREOF, **LEXON INSURANCE COMPANY** has caused this instrument to be signed by its President, and its Corporate Seal to be affixed this 2nd day of July, 2003.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

LEXON INSURANCE COMPANY

BY _____
David E. Campbell
President

ACKNOWLEDGEMENT

On this 2nd day of July, 2003, before me, personally came David E. Campbell to me known, who being duly sworn, did depose and say that he is the President of **LEXON INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he executed said instrument on behalf of the corporation by authority of his office under the By-laws of said corporation.

"OFFICIAL SEAL"
MAUREEN K. AYE
Notary Public, State of Illinois
My Commission Expires 09/21/09

_____
Maureen K. Aye
Notary Public

CERTIFICATE

I, the undersigned, Secretary of **LEXON INSURANCE COMPANY**, A Texas Insurance Company, DO HEREBY CERTIFY that the original Power of Attorney of which the foregoing is a true and correct copy, is in full force and effect and has not been revoked and the resolutions as set forth are now in force.

Signed and Sealed at Lombard, Illinois this 31st Day of Oct., 20 08.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

_____
Donald D. Buchanan
Secretary

TEL: (201) 653-6100
BOND FAX: (201) 653-7766
MARINE FAX: (201) 533-8611

EMAIL: bond@intlbondmarine.com
marine@intlbondmarine.com

INTERNATIONAL BOND & MARINE BROKERAGE, LTD.
Two Hudson Place • 4th Floor • Hoboken, NJ 07030-5515
www.intlbondmarine.com

October 28, 2008

Via Certified Mail / RRR
7005 1820 00006 2888 3457

Attn: Candy
Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, NV 89509 - 3766

Re: Kuehne + Nagel, Inc.
Pharmaceutical Wholesaler Surety Bond
Bond # 413722

Dear Candy:

Enclosed please find the Change in Surety Rider and power of attorney for the above captioned bond. Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company Bond as of the anniversary date of October 31st, 2008. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount remain unchanged.

If you have any questions or require additional information please feel free to contact our office.

Sincerely,

Shayna Betancourt

Shayna Betancourt
Assistant Surety Manage
International Bond & Ma

Enclosure

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:
Attn: Candy
Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, NV 89509

COMPLETE THIS SECTION ON DELIVERY

A. Signature X — ☐ Agent ☐ Addressee

B. Received by (Printed Name) L. Hedan — C. Date of Delivery NOV 03 2008

D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

3. Service Type
☑ Certified Mail ☐ Express Mail
☑ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7005 1820 0006 2888 3457

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

"SERVING THE

Lexon Insurance Company
(a TX Corporation)
256 Jackson Meadows Drive
Hermitage, TN 37076

Bond Rider

Principal: KUEHNE + NAGEL, INC.
Bond Number: 413722
Effective Date of Rider: 10/31/08

Change in Surety

Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company as of the above referenced effective date of the rider. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount, remain unchanged.

Nothing herein contained otherwise shall be held to vary, alter, waive, or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond.

Lexon Insurance Company
Attorney-in-fact, Kevin A. Tattam 143-48-7151

By: _____

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/03/2025

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

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

PRODUCER	CONTACT NAME: Felicia Brown	
Nacora Insurance Brokers Inc 10 Exchange Place, 20th Floor Jersey City NJ 07302	PHONE (A/C, No, Ext): 201-413-0535	FAX (A/C, No): fax number
	E-MAIL ADDRESS: felicia.brown@nacora.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Zurich American Insurance Company	16535
	INSURER B: American Guarantee & Liability Ins. Co.	26247
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

INSURED
Kuehne + Nagel, Inc. c/o Nacora Insurance Brokers, Inc 10 Exchange Place, 20th Floor Jersey City NJ 07302

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR			GLO3373970	1/01/2025	1/01/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
	X $5,000: BI/PD Deductible						MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	2,000,000
	OTHER:							$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
B	X UMBRELLA LIAB X OCCUR			AUC379310315	1/01/2025	1/01/2026	EACH OCCURRENCE	$	20,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	20,000,000
	DED X RETENTION $ 0							$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	
							E.L. DISEASE - POLICY LIMIT	$	
A	Property (PD & TE)			MCP2906577-26	1/01/2025	1/01/2026	BLANKET LIMIT		$135,805,200

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: 324 Half Acre Road, Cranbury NJ 08512; 2525 Whilden Drive, Durham NC 27713
DFW: 2600 Regent Blvd, Dallas, TX 75261
MEM: 6005 Freeport Ave, Suite 103, Memphis, TN 38141
LJV: 1800 Waters Ridge Dr, Suite 100, Lewisville, TX 75057
SVQ: 4080 Executive Drive, Suite 100, Southaven, MS 38672
PAF: 1025 Columbia Road, Suite 110, Plainfield, IN, 46168
RNO: 2555 USA Parkway, #104, McCarran, NV 89434
Property Coverage includes Business Personal Property and Loss of Business Income & Extra Expense per schedule on file.

CERTIFICATE HOLDER

Wyoming Board of Pharmacy
1712 Carey Avenue, Suite 200
Cheyenne, WY 82002

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Kuehne+Nagel Inc. MDEG License # (if applicable) WH01152

Physical Address 1800 Waters Ridge Dr. Ste 100

City Lewisville State TX Zip 75057

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Sharon Middle Watson Last McCabe

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

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

Mailing Addres [redacted]

City Lewisville State TX Zip [redacted]

Telephon [redacted] Email sharon.mccabe@kuehne-nagel.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Barton College		1983-1986	
Address	**City**	**State**	**Zip**
400 Atlantic Christian College Dr NE	Wilson	NC	27893
Diploma/Degree obtained, if any			
B.S. Chemistry, Mathematics Minor			

School Name		From - To (MM/YY – MM/YY)	
North Carolina State University		1988-1989	
Address	**City**	**State**	**Zip**
2310 Stinson Dr	Raleigh	NC	27695
Diploma/Degree obtained, if any			
Coursework towards M.S. in Chemistry			

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

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

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

N/A
04-Feb-2025

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/15-present	[redacted]	Lewisville	TX	[redacted]
01/13-01/15		Plano	TX	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A
04-Feb-2025

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

Business Name: Kuehne+Nagel Inc.			From - To (MM/YY – MM/YY): 07/23-present
Business Address: 1800 Waters Ridge Dr. Ste 100	City: Lewisville	State: TX	Zip: 75057
Phone: 972-459-7655	Title: Sr. Quality Manager		Number of Employed Hours: >4000
Description of Duties: Sr. Quality Manager for Third Party Logistics (3PL), 320 employee/35 Quality Team members, single-client Distribution Center responsible for Quality System oversite of Rx/OTC, Medical Device, Tissue, Biologicals, Skin Care, and Dietary Supplements including kitting, repack/relabeling, reverse distribution, quality inspection, change control, validation, and sampling protocols according to 21 CFR. As key member of Sr. Leadership team, responsible for site Product Quality, GxP compliance, Quality plans, Business Continuity, HIPAA, Quality reporting including CAPA, metrics, and site licensing (Designated Representative). FDA Management Representative hosting/supporting 59 audits since 2017 from State/Federal, Internal and External Regulatory groups. Regional Audit Site preparedness Quality Management for sister KN HealthChain sites throughout US.			

Business Name: Kuehne+Nagel Inc.			From - To (MM/YY – MM/YY): 10/17-07/23
Business Address: 1800 Waters Ridge Dr. Ste 100	City: Lewisville	State: TX	Zip: 75057
Phone: 972-459-7635	Title: Quality Assurance Manager		Number of Employed Hours: >12,000
Description of Duties: Quality Assurance Manager for Third Party Logistics (3PL), 320 employee/35 Quality Team members, single-client Distribution Center responsible for Quality System oversite of Rx/OTC, Medical Device, Tissue, Biologicals, Skin Care, and Dietary Supplements including kitting, repack/relabeling, reverse distribution, quality inspection, change control, validation, and sampling protocols according to 21 CFR. As key member of Sr. Leadership team, responsible for site Product Quality, GxP compliance, Quality plans, Business Continuity, HIPAA, Quality reporting including CAPA, metrics, and site licensing (Designated Representative). FDA Management Representative hosting/supporting 59 audits since 2017 from State/Federal, Internal and External Regulatory groups. Regional Audit Site preparedness Quality Management for sister KN HealthChain sites throughout US			

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

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

04-Feb-2025

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

Continue on next page if additional space is needed.

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

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

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

N/A

04-Feb-2025

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

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

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

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

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

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

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

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

Provide explanation below:

Sharon McCabe — Original Signature (electronic, copies or stamps not accepted)

04-Feb-2025 — Date

I, Sharon McCabe, **certify that as the MDEG Administrator for**

Kuehne+Nagel Inc.,

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

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

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

Sharon McCabe
Print Name (First, Last)

Sharon McCabe
Original Signature (electronic, copies or stamps not accepted)

04-Feb-2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kuehne + Nagel Inc.

Pharmacy/Wholesaler License # (if applicable) WH01152

Physical Address 1800 Waters Ridge Dr, Suite 100

City Lewisville State TX Zip 75057

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Sharon Middle Watson Last McCabe

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

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

Mailing Address [redacted]

City Lewisville State T X Zip [redacted]

Telephon[redacted] Email sharon.mccabe@kuehne-nagel.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Barton College		1983-1986	
Address	**City**	**State**	**Zip**
400 Atlantic Christian College Dr NE	Wilson	NC	27893
Diploma/Degree obtained, if any			
B.S. Chemistry, Mathematics Minor			

School Name		From - To (MM/YY – MM/YY)	
North Carolina State University		1988-1989	
Address	**City**	**State**	**Zip**
	Raleigh	NC	27695
Diploma/Degree obtained, if any			
Coursework towards M.S. in Chemistry			

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

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

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

14-Nov-2024

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/15 to present	[redacted]	Lewisville	TX	[redacted]
01/13 to 01/15		Plano	TX	
N/A				

14-Nov-2024

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

Business Name			From - To (MM/YY – MM/YY)
Kuehne + Nagel Inc.			07/23-Present
Business Address	**City**	**State**	**Zip**
1800 Waters Ridge Dr, Suite 100	Lewisville	TX	75057
Phone	**Title**	**Number of Employed Hours**	
972-459-7635	Sr. Quality Manager		
Description of Duties	Sr. Quality Manager for Third Party Logistics (3PL), 320 employee/35 Quality Team members, single-client Distribution Center responsible for Quality System oversite of Rx/OTC, Medical Device, Tissue, Biologicals, Skin Care, and Dietary Supplements including kitting, repack/relabeling, reverse distribution, quality inspection, change control, validation, and sampling protocols according to 21 CFR. As key member of Sr. Leadership team, responsible for site Product Quality, GxP compliance, Quality plans, Business Continuity, HIPAA, Quality reporting including CAPA, metrics, and site licensing (Designated Representative). FDA Management Representative hosting/supporting 59 audits since 2017 from State/Federal, Internal and External Regulatory groups. Regional Audit Site preparedness Quality Management for sister KN HealthChain sites throughout US.		

Business Name			From - To (MM/YY – MM/YY)
Kuehne + Nagel Inc.			10/17-07/23
Business Address	**City**	**State**	**Zip**
1800 Waters Ridge Dr, Suite 100	Lewisville	TX	75057
Phone	**Title**	**Number of Employed Hours**	
972-459-7635	Quality Assurance Manager		
Description of Duties	Sr. Quality Manager for Third Party Logistics (3PL), 320 employee/35 Quality Team members, single-client Distribution Center responsible for Quality System oversite of Rx/OTC, Medical Device, Tissue, Biologicals, Skin Care, and Dietary Supplements including kitting, repack/relabeling, reverse distribution, quality inspection, change control, validation, and sampling protocols according to 21 CFR. As key member of Sr. Leadership team, responsible for site Product Quality, GxP compliance, Quality plans, Business Continuity, HIPAA, Quality reporting including CAPA, metrics, and site licensing (Designated Representative). FDA Management Representative hosting/supporting 59 audits since 2017 from State/Federal, Internal and External Regulatory groups. Regional Audit Site preparedness Quality Management for sister KN HealthChain sites throughout US.		

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

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

N/A

14-NOV-2024

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

Continue on next page if additional space is needed.

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

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

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

14-Nov-2024

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

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

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

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

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

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

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

Provide explanation below:

N/A

14-Nov-2024

Sharon McCabe

Original Signature (electronic, copies or stamps not accepted)

14-Nov-2024

Date

I, Sharon McCabe, **certify that as the designated representative for**

Kuehne + Nagel Inc.,

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

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

Sharon McCabe

Print Name (First, Last)

Sharon McCabe

Original Signature (electronic, copies or stamps not accepted)

14 Nov 2024

Date

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

Sharon McCabe

Print Name (First, Last)

Sharon McCabe — 14. Nov. 2024

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

---

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

State of Texas, ss. County of Denton

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

Sharon McCabe — 14. Nov. 2024

Original Signature — **Date**

Subscribed and Sworn to before me this 14 day of November 2024

Nola K Burton

Notary Public Signature

NOLA K BURTON
Notary ID #133191990
My Commission Expires
July 6, 2025

(Seal)

LEWISVILLE
EMPLOYEE NAMES
Abundis Rodriguez, Ezequiel
Abundiz, Aaron
Aguirre, Rosa
Alana, Lisbany
Alex, Alan
Alex, Mony
Ali, Amber
Ali, Asif
Ali, Rozeena
Al-Sadawi, Daniel D
Altieri, Kenneth
Alvarado, Lilian
Alvarez, Alberto
Alvarez, Julie
Amaya, Rosa M
An, Jianwei
Anderson, Lillian R
Arballo, Amelia
Archer, Bridgette
Arias Bonilla, Kenia G
Asif, Khursheed
Avalos, Juan J
Bagheri Ghalatpaeini, Nader
Baladez, Juan
Balasubramaniam, Pratheepan
Barba, Maribel
Barboza, Siole
Barclay, Kevin W
Barrientos, Angelica S
Barrientos, Gedver
Barron, Cordarrell
Barron, Rosa
Bell, Denver
Bell, Dudley G
Benitez, Petra
Bennett, Walter L
Berlanga, Andrew A
Boardley Chantray
Boe, Kristin
Boscan, Monica
Bracho, Yennys
Bronner, Kaidynce
Bravo, Maribel
Bruno, Elijah

Buckley, Michael P
Burton, Nola
Bustos, Jenna R
Camacho, Ines
Cano, Candelario G
Carrasco, Damelis
Carrizo, Eddy
Carvajal, Ana
Castillo, Alma P
Castillo, Erina
Castillo, Lisbeth
Chanon, Ivan
Chavira, Juan
Chirino, Rosa
Chourio, Yuleny
Clark, Christiopher
Clemons, Bonnie G
Corr, Makala
Cory, Robb E
Coursey, Kent D
Crawford, Claire
Cruz, Anna C
Cuevas, Maria G
Davis, Amy
Davis, Tyrone
De La Fuente, Gloria E
De La Garza, Claudia B
Debose, Anna M
Delgadillo, Irma I
Diaz, Alondra J
Diaz, Anna
Domond, Peggy R
Dowell, Kailen
Echaide, Indira
Elayathampy, Vijithan
Elgueta, Alfredo A
Elias, Ana M
Elizondo, Nohemi G
Espinoza, Maria
Espy, Gregory
Estrada, Antonio J
Estrada, Jorge
Fincher, Dennis
Fisher, Bryant
Flores, Lourdes
Flores, Mary
Fox, Loren D

Fuentes, Rosa E
Gainza, Norel
Galvan, Maria
Gaskill, Irene
Gleciano, Nilda J
Gomez, Kameron
Gonzalez, Monica M
Gouldthorpe, Christine A
Gray, Ravan
Guerrero, Marely
Guevara, Domingo V
Guiterriez, Jesus
Gutierrez Dos Santos, Suam
Gutierrez, Chris
Guzman, Roberto H
Habeger, James P
Ham, Somany
Hamm, Charlotte A
Hassan, Saba
Hernandez, Jose
Hernandez, Teresa I
Hernandez, Yildred
Herrera, Andrew
Herrera, Kevin
Ibanez, Maria
Ibrahim, Salma B
Ihemadu, Chelsea
Ikpo, Chinedu
Jaimes, Aislinn J
Jaimes, Felix D
Jimenez, Diosita
Jimenez, Yohander
Johnson, Dijonna
Juarez, Aida
Juarez, Deisy
Kabiruddin, Muhammad
Kallikkadan, John F
Khan, Muhammad S
Koinange, Nicholas
Kopsky, Kevin
Krishnakumar, Tharsini
Lakhani, Nadeem
Lalani, Rozmeen P
Langat, Denis K
Legbara, Leton
Lehberg, Alexandria
Loera, Victor

Lopez Morales, Diana
Luke, Mani
Lum, Alexis R
Lynn, Christine
Macias, Baltazar
Mahmood, Fazal
Makani, Rozina
Manar, Bu
Mang, Cung
Manning, Chiniqua
Marez, Elizabeth A
Marin, Mary
Marquez, Mario
Martinez, Angel
Martinez, Arturo
Martinez, Faviola
Martinez, Gabriela
Martinez, Heriberto
Martinez, Jacob
Martinez, Lorena
Mata, Beatriz
Mata, Ricardo
Maxwell, Kenneth
McCabe, Sharon W
McCoy, Jermi D
McCoy, Tanisha
Medina, Graciela E
Mendoza, Nicolas J
Monslave, Emma
Montiel, Argelis
Montiel, Indianis
Moran, Lisbella
Moreno De Jaimes, Olga J
Moreno Hernandez, Claudia A
Moreno. Jose
Moz, Mayra
Mushtaq, Fnu
Mushtaq, Salma
Mwaura, Maryann
Nanez, Rolando A
Nguyen-Luong, Kiet K
Nirbarger, Erik
Norris, Kevin
Nyang, Tinmar
Orbe, Ennie
Ortiz, Baylea
Osorio, Esther

Osorio, Genesis
Osornia, Maria E
Pacheco, Iderkee
Padhani, Rubina
Panzer, Blaine
Parajuli, Anuj
Patel, Nareshbhai K
Perez, Jonathan-Kenneth
Perez, Yamilex
Pernalette, Dilcia
Pernalette, Ingrid
Pinaga, Christian W
Pollard, Jaraad
Portorreal, Juan
Price, Rebecca A
Rangel, Manuel A
Raudales, Roberto C
Reynafarje, Dulce M
Reynafarje, Eduardo
Rhew, Megan
Rivera, Maria J
Robinson, Shane
Robles, Fernanda
Robles, Ricardo
Robles, Teresita D
Rodriguez, Tatiana
Roman, Omayra
Romero, Janette C
Romero, Jolynnn C
Romero, Judy
Romero, Natalia
Rosales, Angela
Ruiz, Mary
Salazar Arrivillaga, Carlos R
Saleem, Sadia
Sanchez, Crystal
Santana, Maricela
Santana, Sulma S
Sloan, Ke'Darius
Smotherman, Travier
Sustaita, Isaac J
Tawng, Seng
Taylor, Wendy
Telles, Marycarling
Thanabalasingam, Sarveswaran
Thomas, Mariamma
Thompson, Danny

Torres, David A
Torres-Rivera Maria
Tovar, Andreina
Tovar, Mariangela
Trejo, Yrasema
Tua, Maria
Valdez, Julia C
Vargas, Stefhania
Vasquez Reyes, Aniorfi
Vejegas, Carlos
Velazquez, Gustavo
Villalobos, Ana
Wages, Garrett
Walker, Rodney
Wesley, Brian
White, Gary L
Williams, Lynvoll
Wiser, David S
Woelper, Freddy
Wright, Arkemius
Yanez, Guillermina
Yepez, Luis
Zurita, Amado

4M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 00941	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Kuehne + Nagel Inc.

Physical Address: 6005 Freeport Ave, Suite 103

City: Memphis State: TN Zip: 38141

Mailing Address (if different from physical address): 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 901-794-1160 Website: https://us.kuehne-nagel.com/

Name of Designated Representative (DR): Sekether Jackson

Licensing Company Email: qshepharma.us@kuehne-nagel.com DR Email: sekether.jackson@kuehne-nagel.

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3rd Party Logistics Provider

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/18/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Lifescan Global Corporation
Address: 20 Valley Stream Parkway City: Malvern State: PA Zip: 19355

Name: AstraZeneca US
Address: 1800 Concord Pike City: Wilmington State: DE Zip: 19850

Name: Moderna
Address: 325 Binney Street City: Cambridge State: MA Zip: 02142

Name: Endo Pharmaceuticals Inc
Address: 1400 Atwater Dr City: Malvern State: PA Zip: 19355

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): Kuehne + Nagel Holdings Inc.
Corporation/Organization Name: Kuehne + Nagel Inc.
Mailing Address: 10 Exchange Place 20th Floor
City: Jersey City State: NJ Zip: 07302
Telephone: 201-413-5500 Email: qshepharma.us@kuehne-nagel.com
Contact Person Name: Natalie Martino

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kuehne + Nagel Inc.

Facility Name

Dan Osterberg

Print Name of Authorized Person Submitting Application

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

11/18/2024

Date

Board Use Only	Date Received: 12/5/24	Amount: $1000 - ck 13448

NABP ACCREDITED
DRUG DISTRIBUTOR

Kuehne + Nagel, Inc

located at

6005 Freeport Ave, Suite 103, Memphis, TN 38141

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

05/11/2022 to 05/10/2025
Period of Accreditation

KUEHNE+NAGEL

Owner:
Kuehne + Nagel Investment, LLC
10 Exchange Place 19th floor, Jersey City NJ 07302
FEIN: 22-3176791
100% Ownership

List of Officers:

Marcus Bennett, President/CEO

[redacted]

Dan Osterberg, CFO

[redacted]

Richard J Kaluzinski, Secretary, National Legal Counsel

[redacted]

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	KUEHNE + NAGEL INC.
DOS ID Number:	200052
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/30/1966
Effective Date:	05/01/2023
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 16, 2024 at 04:29 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006589450 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

KUEHNE+NAGEL

Kuehne+Nagel U.S. Legal Structure

September 1, 2024

KUEHNE+NAGEL

Anticipated Kuehne+Nagel U.S. Legal Structure

December 1, 2024

KUEHNE+NAGEL

Kuehne + Nagel Inc.

10 Exchange Pl
Floor 20
Jersey City, NJ 07302

Tel.: +1 484.995.6137
ria.philip@kuehne-nagel.com

us.kuehne-nagel.com
www.kuehne-nagel.com

AGREEMENT
AND
PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER, dated as of November 11, 2024 (this "Plan of Merger"), is between Kuehne + Nagel Investment LLC, a New Jersey Limited Liability Company ("Merged LLC"), and Kuehne + Nagel Holdings, Inc., a Delaware corporation ("Surviving Corporation").

W I T N E S S E T H:

WHEREAS, Merged LLC has a single member to wit, the Surviving Corporation; and

WHEREAS, Surviving Corporation is authorized to issue a total of 100 shares of capital stock, consisting of 200 shares of common stock, par value $0.01 per share ("Surviving Corporation Common Stock"), of which, as of the date hereof, 100 shares of Common Stock are issued and outstanding; and

WHEREAS, the sole member and the Managers of the Merged LLC and the Board of Directors of the Surviving Corporation, respectively, approve and deem it advisable that Merged LLC and Surviving Corporation, respectively, consummate the Merger (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements contained in this Plan of Merger, the parties to this Plan of Merger hereby agree that Merged LLC shall be merged (the "Merger") with and into Surviving Corporation in accordance with applicable laws and upon the terms and subject to the conditions set forth as follows:

1. The Merger. At such time agreed between Merged LLC and Surviving Corporation, a certificate of merger evidencing the Merger shall be filed with each of the Office of the Secretary of State of the State of New Jersey pursuant to the Title 42 of the New Jersey Revised Statutes and of the State of Delaware General Corporation Law. The Certificates of Merger shall specify that the Merger shall become effective on December 1, 2024 ("Effective Time"). At the Effective Time, Merged LLC shall be merged with and into Surviving Corporation, and Surviving Corporation shall continue as the surviving corporation. The Surviving Corporation's name shall remain Kuehne + Nagel Holdings, Inc.

2. Certificate of Incorporation and By-laws. The Certificate of Incorporation and By-laws of Surviving Corporation in effect immediately prior to the Effective Time shall be and remain the Certificate of Incorporation and By-laws, respectively, of Surviving Corporation, as the surviving corporation, after the Effective Time, until amended as provided by law.

3. Officers and Directors. From and after the Effective Time, and until they shall have resigned or shall have been legally removed or until their respective successors shall have been elected or appointed and qualified, those persons who are the officers and directors of Surviving Corporation immediately prior to the Effective Time shall be the officers and directors of Surviving Corporation.

4. Effect of the Merger.

4.1 All assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC in and to every type of property (real, personal and mixed) and choses in action, as they exist as of the Effective Time, shall pass and be transferred to and vest in Surviving Corporation, as the surviving corporation, by virtue of the Merger at the Effective Time without any deed, conveyance or other transfer, and all such interests of Surviving Corporation as they exist as of the Effective Time shall remain with Surviving Corporation upon consummation of the Merger. The corporate existence of Surviving Corporation shall continue unaffected and unimpaired upon consummation of the Merger and the separate corporate existence of Merged LLC shall cease at and as of the Effective Time.

4.2 From and after the Effective Time, Surviving Corporation, as the surviving corporation, shall be responsible and liable for all of the liabilities and obligations of Surviving Corporation and Merged LLC existing as of the Effective Time. Any claim existing or action or proceeding pending by or against Surviving Corporation or Merged LLC at the Effective Time may, thereafter, be prosecuted by or against Surviving Corporation, as the surviving corporation, as if the Merger had not taken place or, in connection with any such action or proceeding to which Merged LLC is a party, Surviving Corporation, as the surviving corporation, may be substituted in place of Merged LLC. Neither the rights of creditors nor any liens upon the property of either Surviving Corporation or Merged LLC shall be impaired by reason of the Merger.

5. Effect of Merger on Outstanding Shares.

5.1 *Exchange Ratio*. At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof, all of the issued and outstanding member shares of the Merged LLC shall be cancelled.

5.2 *Closing of Transfer Books*. At the Effective Time, the membership transfer books of Merged LLC shall be closed and no transfer of shares of Merged LLC membership shall thereafter be made. If, after the Effective Time, certificates representing member shares of Merged LLC are presented to the Surviving Corporation, they shall be canceled in accordance with the terms hereof. At and after the Effective Time, the holders of member shares of Merged LLC Stock shall cease to have any rights as members of Merged LLC.

6. Further Assurances. From time to time after the Effective Time, as and when requested by Surviving Corporation, and to the extent permitted by law, the former managers of Merged LLC and the officers and directors of Surviving Corporation shall execute and deliver such assignments, deeds and other instruments and shall take or cause to be taken such further or other action as shall be necessary in order to consummate the Merger, vest or perfect in or to confirm of record or otherwise to Surviving Corporation, as the surviving corporation, title to, and possession of, all of the assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC and Surviving Corporation in and to every type of property (real, personal and

mixed) and choses in action, and otherwise to carry out the purposes of this Plan of Merger, and the proper officers and directors of Surviving Corporation, as the surviving corporation, are fully authorized to take any and all such action in the name of Merged LLC or Surviving Corporation or otherwise.

7. Termination and Amendment. Prior to the Effective Time, this Plan of Merger may be terminated or amended by the mutual consent of the Managers of Merged LLC and the Board of Directors of Surviving Corporation.

8. Counterparts. This Plan of Merger may be signed in any number of counterparts, each of which shall be deemed an original, and all of which shall be deemed but one and the same instrument.

9. Governing Law. This Plan of Merger shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New Jersey or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New Jersey.

IN WITNESS WHEREOF, the parties have duly executed this Plan of Merger as of the date first written above.

KUEHNE + NAGEL INVESTMENT LLC
(Merged LLC)

By: _____
Marcus Bennett, Manager

By: _____
Dan Osterberg, Manager

By: _____
Nadine Jones, Manager

KUEHNE + NAGEL HOLDINGS, INC.
(Surviving Corporation)

By: _____
Name: Dan Osterberg
Title: CFO, Treasurer

State of Tennessee
Department of Health

14182844

Renewal No. 35898

Board of Pharmacy
Third Party Logistics

KUEHNE + NAGEL INC.
6005 FREEPORT AVE #103,
MEMPHIS, TN 38141

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 1554

EXPIRATION DATE: November 30, 2026

Commissioner, Dept. of Health

Jennifer L. Rotnam, Esq
Assistant Commissioner, Health Licensure & Regulation

Last Updated: 3/19/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 8

Click here to return to the search page

1

Kuehne + Nagel Inc.
2532 Whilden Drive
Durham, NC 27713
Attn: Michael Tad Ruble
919-957-3312

Rank: Third Party Logistics

Facility License Number: 00008923
Status: Licensed
Date of Original Licensure: 02/24/2023
Date of Expiration: 11/30/2026
No Disciplinary Actions

2

Kuehne + Nagel Inc
4080 Executive Dr Ste 100
Southaven, MS 38672
Attn: Stephen Berry
662-985-9936

Rank: Third Party Logistics

Facility License Number: 00007891
Status: Licensed
Date of Original Licensure: 04/19/2022
Date of Expiration: 11/30/2026
No Disciplinary Actions

3

Kuehne + Nagel Inc
1025 Columbia Rd, Suite 110
Plainfield, IN 46168
Attn: Scott Evans
317-754-4034

Rank: Third Party Logistics

Facility License Number: 00008846
Status: Licensed
Date of Original Licensure: 03/17/2023
Date of Expiration: 11/30/2026
No Disciplinary Actions

4

Kuehne + Nagel Inc
2600 Regent Blvd
Dallas, TX 75261
Attn: Angel Martinez
630-965-3804

Rank: Third Party Logistics

Facility License Number: 00009420
Status: Licensed
Date of Original Licensure: 08/21/2023
Date of Expiration: 11/30/2026
No Disciplinary Actions

5

KUEHNE + NAGEL INC.
6005 FREEPORT AVE Suite 103/104
Memphis, TN 38141
Attn: Sekether Jackson
901-794-1160

Rank: Third Party Logistics

Facility License Number: 00001554
Status: Licensed

List of Licences-MEM

Jurisdiction	Requirement	Number	Issue Date	Expiration Date
US-AL	Third Party Logistics Provider	193056	03/19/2004	12/31/2024
US-AR	Wholesale Distributor	WD02254	04/14/2000	12/31/2024
US-AZ	Third Party Logistics Provider	L000002	08/31/2017	10/31/2025
US-CA	Third Party Logistics Provider	NPL 1015	07/31/2015	07/01/2025
US-CO	Third Party Logistics Provider	TPLP.0000100	07/23/2024	10/31/2026
US-CT	Wholesaler of Drugs, Cosmetics, & Medical Devices	CSW.0001205	07/01/2024	06/30/2025
US-DC	Non-Resident Distributor	DM0000586	11/30/2011	11/30/2024
US-DE	Pharmacy - Wholesale	A4-0000779	04/04/2000	09/30/2026
US-FL	Third Party Logistics Provider	0212	12/12/2008	12/31/2024
US-GA	Wholesaler Pharmacy	PHWH001412	04/14/2000	06/30/2025
US-IA	Third Party Logistics Provider	80045	04/11/2019	03/31/2025
US-IL	Wholesale Drug Third Party Logistics Provider	278000047	10/18/2021	12/31/2024
US-IN	Third Party Logistics Provider	94000276A	02/12/2024	09/30/2026
US-KS	Third Party Logistics Provider	23-01298	06/29/2020	06/30/2025
US-KS	Sample Distributor	15-123124	05/28/2024	06/30/2025
US-KY	Third Party Logistics Provider	TPL00141	08/31/2017	06/30/2025
US-LA	Third Party Logistics Provider	3339	10/14/2001	12/30/2024
US-MI	Wholesale Distributor	5306001771	06/08/2000	06/08/2026
US-MN	Third Party Logistics Provider	900097	05/19/2020	10/31/2025
US-MO	Third Party Logistics Provider	2000155381	04/05/2001	10/31/2025
US-MS	Third Party Logistics Provider	16166	07/14/2017	12/31/2024
US-MT	Wholesale Drug Distributor	PHA-WDD-LIC-2165	11/21/2006	11/30/2024
US-NC	Third Party Logistic Provider	317	12/08/2023	12/31/2024
US-ND	Third-Party Logistic Provider	TPL472	07/01/2004	06/30/2025
US-NH	Manufacturer / Distributor / Wholesaler / Broker	06919	05/18/2020	06/30/2026
US-NM	Third Party Logistics Provider	WD00010167	11/06/2001	12/31/2025
US-NM	Third Party Logistics Provider	WD00010167	11/06/2001	12/31/2025
US-NV	Wholesaler	WH00941	04/27/2000	10/31/2026
US-OH	Third-Party Logistics - Category 2	011206550	05/17/2000	06/30/2025
US-OK	Third Party Logistics Provider	88-L-8550	06/03/2024	06/30/2025
US-OR	Drug Distribution Agent	DDA-0000118	10/01/2015	09/30/2025
US-PA	Distributor of Prescription Drugs	3000007197	10/09/2001	01/31/2025
US-SC	Non-Resident Third Party Logistics Provider	7508	05/30/2004	06/30/2025
US-TN	Third Party Logistics Provider	00001554	03/30/2000	11/30/2024
US-TX	Out of State Prescription	0043318	06/09/2000	12/31/2024
US-UT	Pharmacy - Class C	9115331-1710	08/18/2014	09/30/2025
US-VA	Third Party Logistics Provider	0242000039	06/24/2019	02/28/2025
US-VT	Third Party Logistics Provider	159.0000074	07/31/2019	07/31/2025
US-WI	Wholesale Distributor of Prescription Drugs	1828-45	08/14/2005	05/30/2026
US-WV	Third Party Logistics Provider	3PL0000008	06/18/2024	06/30/2026
US-WY	Third Party Logistics Provider	3PL0083	06/18/2024	06/30/2025

Lexon Insurance Company

November 20, 2024

Nevada Board of Pharmacy

Bond Name: KUEHNE + NAGEL INC.
Bond Number: 413722
Amount: $100,000.00
Effective Date: 10/31/2006

Rider Executed and Effective November 20, 2024

The above referenced bond includes the following K+N facility location to ensure sufficient coverage:

1025 Columbia Rd, Suite 110, Plainfield, IN 46168

4080 Executive Drive, Suite 100, Southaven, MS 38672

2555 USA Parkway, Suite 104, McCarran, NV 89434

324 Half Acre Road, Cranbury, NJ 08512

2532 Whilden Drive, Durham, NC 27713

6005 Freeport Avenue, Suite 103, Memphis, TN 38141

2600 Regent Blvd Dallas, TX 75261

1800 Waters Ridge Drive, Suite 100, Lewisville, TX 75057

Nothing herein contained shall be held to vary, alter or waive or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond or policy, other than as above stated.

Lexon Insurance Company

James Reiss, Attorney in Fact

By:

NEVADA STATE BOARD OF PHARMACY

885 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0413722

Application/License No. WH00941

Kuehne + Nagel Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
6005 Freeport Ave #J-122, Memphis TN 38141, as
Address of Applicant/Principal
PRINCIPAL, and International Fidelity Insurance Co., a
Surety Company
corporation organized under the laws of the state of New Jersey
State of Incorporation
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
One Newark Center, Newark NJ 07102 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on _____.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL

_____
Authorized Representative

SURETY COMPANY

International Fidelity Ins. Co.
Surety Company's Representative

Kevin A. Tattam, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Benny Munoz
Witness

Martino Sessa
Witness

Countersigned by:

Nevada Resident Agent

NEVADA BONDING AGENCY, INC.
P.O. BOX 60987
LAS VEGAS, NV 89160
PHONE (702) 631-0878
FAX (702) 647-5301

POWER OF ATTORNEY

LX - 015431

Lexon Insurance Company

KNOW ALL MEN BY THESE PRESENTS, that **LEXON INSURANCE COMPANY**, a Texas Corporation, with its principal office in Louisville, Kentucky, does hereby constitute and appoint: Kevin Tattam **********

****

its true and lawful Attorney(s)-In-Fact to make, execute, seal and deliver for, and on its behalf as surety, any and all bonds, undertakings or other writings obligatory in nature of a bond.

This authority is made under and by the authority of a resolution which was passed by the Board of Directors of **LEXON INSURANCE COMPANY** on the 1st day of July, 2003 as follows:

Resolved, that the President of the Company is hereby authorized to appoint and empower any representative of the Company or other person or persons as Attorney-In-Fact to execute on behalf of the Company any bonds, undertakings, policies, contracts of indemnity or other writings obligatory in nature of a bond not to exceed $ 7,100,000.00 Seven million one hundred thousand dollars ..... dollars, which the Company might execute through its duly elected officers, and affix the seal of the Company thereto. Any said execution of such documents by an Attorney-In-Fact shall be as binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company. Any Attorney-In-Fact, so appointed, may be removed for good cause and the authority so granted may be revoked as specified in the Power of Attorney.

Resolved, that the signature of the President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Vice President, and the seal of the Company may be affixed by facsimile to any certificate of any such power and any such power or certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certificate so executed and sealed shall, with respect to any bond of undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS THEREOF, **LEXON INSURANCE COMPANY** has caused this instrument to be signed by its President, and its Corporate Seal to be affixed this 2nd day of July, 2003.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

LEXON INSURANCE COMPANY

BY _____
David E. Campbell
President

ACKNOWLEDGEMENT

On this 2nd day of July, 2003, before me, personally came David E. Campbell to me known, who being duly sworn, did depose and say that he is the President of **LEXON INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he executed said instrument on behalf of the corporation by authority of his office under the By-laws of said corporation.

"OFFICIAL SEAL"
MAUREEN K. AYE
Notary Public, State of Illinois
My Commission Expires 09/21/09

_____
Maureen K. Aye
Notary Public

CERTIFICATE

I, the undersigned, Secretary of **LEXON INSURANCE COMPANY**, A Texas Insurance Company, DO HEREBY CERTIFY that the original Power of Attorney of which the foregoing is a true and correct copy, is in full force and effect and has not been revoked and the resolutions as set forth are now in force.

Signed and Sealed at Lombard, Illinois this 31st Day of Oct., 20 08.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

_____
Donald D. Buchanan
Secretary

TEL: (201) 653-6100
BOND FAX: (201) 653-7766
MARINE FAX: (201) 533-8611

EMAIL: bond@intlbondmarine.com
marine@intlbondmarine.com

INTERNATIONAL BOND & MARINE BROKERAGE, LTD.
Two Hudson Place • 4th Floor • Hoboken, NJ 07030-5515
www.intlbondmarine.com

October 28, 2008

Via Certified Mail / RRR
7005 1820 00006 2888 3457

Attn: Candy
Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, NV 89509 - 3766

Re: Kuehne + Nagel, Inc.
Pharmaceutical Wholesaler Surety Bond
Bond # 413722

Dear Candy:

Enclosed please find the Change in Surety Rider and power of attorney for the above captioned bond. Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company Bond as of the anniversary date of October 31st, 2008. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount remain unchanged.

If you have any questions or require additional information please feel free to contact our office.

Sincerely,

Shayna Betancourt

Shayna Betancourt
Assistant Surety Manage
International Bond & Ma

Enclosure

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
■ Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired. ■ Print your name and address on the reverse so that we can return the card to you. ■ Attach this card to the back of the mailpiece, or on the front if space permits.	A. Signature X ☐ Agent ☐ Addressee B. Received by (Printed Name) L. Hedan C. Date of Delivery D. Is delivery address different from item 1? ☐ Yes ☐ No If YES, enter delivery address below: NOV 03 2008
1. Article Addressed to: Attn: Candy Nevada State board of Pharmacy 431 W Plumb lane Reno, NV 89509	3. Service Type ☐ Certified Mail ☐ Express Mail ☐ Registered ☐ Return Receipt for Merchandise ☐ Insured Mail ☐ C.O.D. 4. Restricted Delivery? (Extra Fee) ☐ Yes
2. Article Number (Transfer from service label) 7005 1820 0006 2888 3457	
PS Form 3811, February 2004 Domestic Return Receipt	102595-02-M-1540

"SERVING THE

Lexon Insurance Company
(a TX Corporation)
256 Jackson Meadows Drive
Hermitage, TN 37076

Bond Rider

Principal: KUEHNE + NAGEL, INC.
Bond Number: 413722
Effective Date of Rider: 10/31/08

Change in Surety

Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company as of the above referenced effective date of the rider. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount, remain unchanged.

Nothing herein contained otherwise shall be held to vary, alter, waive, or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond.

Lexon Insurance Company
Attorney-in-fact, Kevin A. Tattam 143-48-7151

By: _____

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/03/2025

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

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

PRODUCER Nacora Insurance Brokers Inc 10 Exchange Place, 20th Floor Jersey City NJ 07302	**CONTACT NAME:** Felicia Brown **PHONE (A/C, No, Ext):** 201-413-0535 **FAX (A/C, No):** fax number **E-MAIL ADDRESS:** felicia.brown@nacora.com
INSURED Kuehne + Nagel, Inc. c/o Nacora Insurance Brokers, Inc. 10 Exchange Place, 20th Floor Jersey City NJ 07302	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Zurich American Insurance Company — 16535 **INSURER B :** American Guarantee & Liability Ins. Co. — 26247 **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR [X] $5,000: BI/PD Deductible GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			GLO3373970	1/01/2025	1/01/2026	EACH OCCURRENCE	$	1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
							GENERAL AGGREGATE	$	2,000,000
							PRODUCTS - COMP/OP AGG	$	2,000,000
								$	
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$	
							BODILY INJURY (Per person)	$	
							BODILY INJURY (Per accident)	$	
							PROPERTY DAMAGE (Per accident)	$	
								$	
B	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ 0			AUC379310315	1/01/2025	1/01/2026	EACH OCCURRENCE	$	20,000,000
							AGGREGATE	$	20,000,000
								$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE [ ] OTH-ER		
							E.L. EACH ACCIDENT	$	
							E.L. DISEASE - EA EMPLOYEE	$	
							E.L. DISEASE - POLICY LIMIT	$	
A	Property (PD & TE)			MCP2906577-26	1/01/2025	1/01/2026	BLANKET LIMIT		$135,805,200

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

Re: 324 Half Acre Road, Cranbury NJ 08512; 2525 Whilden Drive, Durham NC 27713
DFW: 2600 Regent Blvd, Dallas, TX 75261
MEM: 6005 Freeport Ave, Suite 103, Memphis, TN 38141
LJV: 1800 Waters Ridge Dr, Suite 100, Lewisville, TX 75057
SVQ: 4080 Executive Drive, Suite 100, Southaven, MS 38672
PAF: 1025 Columbia Road, Suite 110, Plainfield, IN, 46168
RNO: 2555 USA Parkway, #104, McCarran, NV 89434
Property Coverage includes Business Personal Property and Loss of Business Income & Extra Expense per schedule on file.

CERTIFICATE HOLDER

Wyoming Board of Pharmacy
1712 Carey Avenue, Suite 200
Cheyenne, WY 82002

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Kuehne+Nagel Inc. MDEG License # (if applicable) WH00941

Physical Address 6005 Freeport Ave, Ste 103

City Memphis State TN Zip 38141

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Sekether Middle Levonta Last Jackson

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

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

Mailing Address [redacted]

City Southaven State MS Zip [redacted]

Telephone [redacted] Email sekether.jackson@kuehne-nagel.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Rosa Fort High School		1994-1997	
Address	**City**	**State**	**Zip**
1100 Rosa Fort Drive	Tunica	MS	38676
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-present	[redacted]	Southaven	MS	[redacted]
1999-2019		Memphis	TN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name: Kuehne+Nagel Inc.			From - To (MM/YY – MM/YY): 01/20-present
Business Address: 6005 Freeport Ave, Ste 103	City: Memphis	State: TN	Zip: 38141
Phone: 901-794-1160	Title: Operations Manager		Number of Employed Hours: >6000
Description of Duties: Serve as the sites' designated representative for Memphis Pharma licenses and maintenance, trainings, and certificates. Manages daily and weekly calls establishing a clear communication channel between Customer and KN to streamline interactions and tasks to be completed efficiently. Complete advanced tasks requiring considerable judgment, problem resolution, independent analysis and decision making while following procedures. Provides day-to-day tactical direction and guidance to Associates for daily workloads; while tracing any shipments at request of the Customer Service Department. Assures the integrity of the inventory and assist in physical inventories by making recommendations on process flow and efficiencies. Comply with all Kuehne & Nagel policies, procedures, safety rules and FDA regulations. Prepare and lead BRM (Business Review Meetings), while managing a pre-defined KPI Dashboard to be shared monthly with key stakeholders within KN.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Sikethu Gaellnas

Original Signature (electronic, copies or stamps not accepted)

2-3-25

Date

I, Sekether Jackson, **certify that as the MDEG Administrator for**

Kuehne+Nagel Inc.,

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

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

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

Sekether Jackson

Print Name (First, Last)

Sekether Jackson

Original Signature (electronic, copies or stamps not accepted)

1-3-25

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kuehne + Nagel Inc.

Pharmacy/Wholesaler License # (if applicable) WH00941

Physical Address 6005 Freeport Ave, Suite 103

City Memphis State TN Zip 38141

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Sekether Middle Levonta Last Jackson

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

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

Mailing Address [redacted]

City Southaven State M S Zip [redacted]

Telephone [redacted] Email sekether.jackson@kuehne-nagel.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Rosa Fort High School		1994-1997	
Address	**City**	**State**	**Zip**
1100 Rosa Fort Dr	Tunica	MS	38676
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019 to present	[redacted]	Southaven	MS	[redacted]
From - To (MM/YY – MM/YY)		City	State	
1999 to 2019		Memphis	TN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Kuehne + Nagel Inc.			01/20-Present
Business Address	**City**	**State**	**Zip**
6005 Freeport Ave, Suite 103	Memphis	TN	38141
Phone	**Title**	**Number of Employed Hours**	
901-794-1160	Operations Manager	>6000	
Description of Duties	Serve as the sites' designated representative for Memphis Pharma licenses and maintenance, trainings, and certificates. Manages daily and weekly calls establishing a clear communication channel between Customer and KN to streamline interactions and tasks to be completed efficiently. Complete advanced tasks requiring considerable judgment, problem resolution, independent analysis and decision making while following procedures. Provides day-to-day tactical direction and guidance to Associates for daily workloads; while tracing any shipments at request of the Customer Service Department. Assures the integrity of the inventory and assist in physical inventories by making recommendations on process flow and efficiencies. Comply with all Kuehne & Nagel policies, procedures, safety rules and FDA regulations. Prepare and lead BRM (Business Review Meetings), while managing a pre-defined KPI Dashboard to be shared monthly with key stakeholders within KN.		

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Arthur F. Jackson
Original Signature (electronic, copies or stamps not accepted)

11-18-2024
Date

I, Sekether Jackson, **certify that as the designated representative for**

Kuehne + Nagel Inc.,

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

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

Sekether Jackson

Print Name (First, Last)

Sekether J. Jackson

Original Signature (electronic, copies or stamps not accepted)

11-18-2024

Date

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

Sekether Jackson
Print Name (First, Last)

Sekether F. Jackson
Original Signature (electronic, copies or stamps not accepted)

11-18-2024
Date

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

State of Mississippi, ss. County of DeSoto

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

Sekether F. Jackson
Original Signature

11-18-2024
Date

Subscribed and Sworn to before me this 18th day of November.

Katelin Wilson
Notary Public Signature

STATE OF MISSISSIPPI
NOTARY PUBLIC
ID# 471914
KATELIN WILSON
Commission Expires
May 23, 2028
DESOTO COUNTY

(Seal)

MEMPHIS
EMPLOYEE NAMES
Agama, Brianna Alyssa V.
Agama Vargas, Oliver
Allen Jr, Michael A.
Amos, Kelsey
Baker, Robert
Bell, Kabrea B.
Bennett, Cynthia
Black, Taronzo
Blaha, Michael D.
Branum, John F.
Brown, Quentin W.
Bynum, Katrina L.
Campbell, Patrick
Castillo, Olga
Coe, Norman
Cox, Justin
Cox, Xavier
Cruz, Roxana R.
Curry, Norma P.
Davis, Dionne D.
Davis, Yaquan
Do, Ngoc M.
Fuller, Terrell T.
Gaulding, Cynthia K.
Gibson, Sabrina R.
Grace, Louie E.
Grafton, Corey L.
Gunn, Joyce
Gwinn, Trixie
Hamer, Elliott T.
Hayes, Radazia
Hobson, Jovan S.
Holland, David D.
Horton, Nehemiah D.
Houston, Margaret L.
Huete, Jacqueline M.
Isom, Tavarus
Jackson, Sekether L.
Johnson, Chelsie R.
Jones, Marcus L.
Jones, Terrick A.
Kenney, Ashawnte D.
Kerr, Marilyn J.
Killpacher, Rodriques

Kimble, Angela R.
Lopez, Maria
Marshall, Justus L.
McClain, Malcolm C.
McCulley, Mary L.
Menzies, Deanna M.
Moody, Katherine
Nelson, Lakesha A.
Nolen-Hall, Ineta
Odom, Cheryl
Oneal, Jadarius
Parham, Kevin
Pendleton, Jacqueline K.
Perkins, Kendra
Philmore, Joshua
Pickens, Lamon D.
Prasse, Herbert F.
Rodgers, Marquisha Q.
Ryans, Marcus A.
Sanders, Sylvester
Smith, Valerie
Spencer, Jessica
Taylor, Michael
Tellis, Jalen
Thomas, Kennedy D.
Tucker, Tangela D.
Twillie, Darrell P.
Williams, Reginald
Woodson, April B.

4N

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☒ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Professional Medical Services + Products Inc. DBA Accellence Home Medical Reno

Physical Address: 5450 Mill St. Unit 101

City: Reno State: NV Zip: 89502

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-787-8880 Website: accellencehomemedical.com

Name of Designated Representative (DR): John Hewitt

Licensing Company Email: jhumphrey@accellencereno.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☒ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-5-2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Matheson Gas
Address: 825 Marietta Way City: Sparks State: NV Zip: 89431
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: Accellence Reno
Mailing Address: 5450 Mill St. Unit 101
City: Reno State: NV Zip: 89502
Telephone: 775-787-8880 Email: jhumphrey@accellencereno.com
Contact Person Name: Julia Humphrey or John Hewitt

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List the top four corporation shareholders and their percent ownership.	✓			
• List of all corporation shareholders and their percent ownership.		✓		
• List of all partners and their percent ownership.			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [1]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [1]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7_1_2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Accellence Home Medical Reno

Facility Name

John Hewitt

Print Name of Authorized Person Submitting Application

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

9.5.2024

Date

Board Use Only	Date Received: 12/30/24	Amount: $1000.00

An official website of the United States government Here's how you know

FDA

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Professional medical*

Showing 1 to 1 of 1 entries (filtered from 2 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Professional Medical Services & Products, Inc.	3003193612	158920194	MANUFACTURE	5450 Mill St Unit 101, Reno, Nevada (NV) 89502-0334, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Jan 17, 2025

New Search

NEVADA

STATE BOARD OF PHARMACY

Medical Devices Equipment Gas

Expires: 10/31/2026

STATUS: Active

Permit Type: Medical Devices Equipment Gas

Permit #: MP00074

Effective Date: 11/01/2024

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

ACCELLENCE HOME MEDICAL - RENO
5450 MILL ST #101
RENO NV 89502

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

Accellence Home Medical

5450 Mill St. Unit 101 ~ Reno, NV 89502 ~ 775-787-8880 ~ Fax 775-352-9333

List of Partners for Accellence Home Medical Reno

Accellence Reno
DBA: Accellence Home Medical Reno
DBA: Accellence Home Medical

Partners: Professional Medical Services & Products, Inc. Ownes 98% John Howitt 2%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **PROFESSIONAL MEDICAL SERVICES & PRODUCTS, INC.** as a DOMESTIC CLOSE CORPORATION (78A) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/15/1997, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 09/16/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409164964240
You may verify this certificate online at https://www.nvsilverflume.gov/home

CERTIFICATE OF REGISTRATION

Professional Medical Services & Products, Inc.

REGISTRATION HAS BEEN CREATED FOR THIS YEAR

2024

such registration has been submitted at the time required by the United States Food and Drug Administration, as per amendments to the Act due to the Food and Drug Administration Safety and Innovation Act (FDASIA) Sec. 701 (I)(A). At such time as the registration is submitted, it will then expire on the last day of 2024.

James Christ

General Manager
Applied Home Healthcare Equipment

2024
Applied Home HEALTHCARE EQUIPMENT
FDA REGISTRATION

Victoria Schulte, Esq.

VICTORIA SCHULTE, ESQ.
CEO & Co-Founder
Applied Home Healthcare Equipment

0626

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
12/11/2024

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

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

PRODUCER
The Millward Agency, Inc.
11142 Highland Blvd
Highland UT 84003

License#: 334384

CONTACT NAME:
PHONE (A/C, No, Ext): 801-216-4545 FAX (A/C, No): 801-216-4275
E-MAIL ADDRESS: certs@millwardagency.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Massachusetts Bay Ins Co	22306
INSURER B : United Financial Casualty Co	11770
INSURER C : Employers	25402
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
HOWJ105000
Professional Medical Service & Products, Inc.
Dba: Accellence Home Medical, Accellence Reno
5450 Mill St #101
Reno NV 89502

COVERAGES **CERTIFICATE NUMBER:** 1898677438 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			ZD4D10910308	12/10/2024	12/10/2025	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER							$
B	AUTOMOBILE LIABILITY			01446028	12/10/2024	12/10/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$ 1,000,000
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			EIG276231705	12/28/2023	12/28/2024	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Professional Liability			ZD4D10910308	12/10/2024	12/10/2025	Limit Aggregate	1,000,000 3,000,000

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

CERTIFICATE HOLDER

Certificate of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Weston Millward

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Accellence Home Medical

5450 Mill St. Unit 101 ~ Reno, NV 89502 ~ 775-787-8880 ~ Fax 775-352-9333

List of Partners for Accellence Home Medical Reno

Accellence Reno
DBA: Accellence Home Medical Reno
DBA: Accellence Home Medical

Partners: Professional Medical Services & Products, Inc. Ownes 98% John Howitt 2%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. EACX3002649

Application/License No. _____

Accellence Home Medical Reno (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5450 Millstreet 101 RENO NV 89502 (Address of Applicant/Principal), as PRINCIPAL, and Endurance Assurance Corporation (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4 Manhattanville Road Purchase NY 10577 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 04/11/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11 day of April, 2024.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Abbey Hoskins
Surety Company's Representative

Abbey Hoskins, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Elizabeth Kelly
Witness

Haley Dahl
Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

SOMPO INTERNATIONAL
INSURANCE

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that **Endurance Assurance Corporation**, a Delaware corporation ("EAC"), **Endurance American Insurance Company**, a Delaware corporation ("EAIC"), **Lexon Insurance Company**, a Texas corporation ("LIC"), and/or **Bond Safeguard Insurance Company**, a South Dakota corporation ("BSIC"), each, a "Company" and collectively, **"Sompo International"** do hereby constitute and appoint: Abbey Hoskins
as true and lawful Attorney(s)-In-Fact to make, execute, seal, and deliver for, and on its behalf as surety or co-surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking so made, executed and delivered shall obligate the Company for any portion of the penal sum thereof in excess of the sum of $ 25,000.00

Such bonds and undertakings for said purposes, when duly executed by said attorney(s)-in-fact, shall be binding upon the Company as fully and to the same extent as if signed by the President of the Company under its corporate seal attested by its Corporate Secretary.

This appointment is made under and by authority of certain resolutions adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC, a copy of which appears below under the heading entitled "Certificate".

This Power of Attorney is signed and sealed by facsimile under and by authority of the following resolution adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolution has not since been revoked, amended or repealed.

RESOLVED, that the signature of an individual named above and the seal of the Company may be affixed to any such power of attorney or any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signature or seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN WITNESS WHEREOF, each Company has caused this instrument to be signed by the following officers, and its corporate seal to be affixed this 25th day of May, 2023.

Endurance Assurance Corporation	Endurance American Insurance Company	Lexon Insurance Company	Bond Safeguard Insurance Company
By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel	By: Richard Appel; SVP & Senior Counsel

Endurance Assurance Corporation CORPORATE SEAL 2002 DELAWARE

Endurance American Insurance Company CORPORATE SEAL 1996 DELAWARE

LEXON INSURANCE COMPANY CORPORATE SEAL MARCH 16, 1964 STATE OF TEXAS

BOND SAFEGUARD INSURANCE COMPANY A SOUTH DAKOTA INSURANCE COMPANY

ACKNOWLEDGEMENT

On this 25th day of May, 2023, before me, personally came the above signatories known to me, who being duly sworn, did depose and say that he/they is an officer of each of the Companies; and that he executed said instrument on behalf of each Company by authority of his office under the by-laws of each Company.

By: Amy Taylor

STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY

Amy Taylor, Notary Public – My Commission Expires 3/9/27

CERTIFICATE

I, the undersigned Officer of each Company, DO HEREBY CERTIFY that:

1. That the original power of attorney of which the foregoing is a copy was duly executed on behalf of each Company and has not since been revoked, amended or modified; that the undersigned has compared the foregoing copy thereof with the original power of attorney, and that the same is a true and correct copy of the original power of attorney and of the whole thereof.
2. The following are resolutions which were adopted by the board of directors of each Company by unanimous written consent effective 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolutions have not since been revoked, amended or modified:
"RESOLVED, that each of the individuals named below is authorized to make, execute, seal and deliver for and on behalf of the Company any and all bonds, undertakings or obligations in surety or co-surety with others: RICHARD M. APPEL, MATTHEW E. CURRAN, MARGARET HYLAND, SHARON L. SIMS, CHRISTOPHER L. SPARRO,
and be it further
RESOLVED, that each of the individuals named above is authorized to appoint attorneys-in-fact for the purpose of making, executing, sealing and delivering bonds, undertakings or obligations in surety or co-surety for and on behalf of the Company."
3. The undersigned further certifies that the above resolutions are true and correct copies of the resolutions as so recorded and of the whole thereof.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal this 11th day of April, 2024.

By: Daniel S. Curie, Secretary

NOTICE: U. S. TREASURY DEPARTMENT'S OFFICE OF FOREIGN ASSETS CONTROL (OFAC)

No coverage is provided by this Notice nor can it be construed to replace any provisions of any surety bond or other surety coverage provided. This Notice provides information concerning possible impact on your surety coverage due to directives issued by OFAC. **Please read this Notice carefully.**
The Office of Foreign Assets Control (OFAC) administers and enforces sanctions policy, based on Presidential declarations of "national emergency". OFAC has identified and listed numerous foreign agents, front organizations, terrorists, terrorist organizations, and narcotics traffickers as "Specially Designated Nationals and Blocked Persons". This list can be located on the United States Treasury's website – https://www.treasury.gov/resource-center/sanctions/SDN-List
In accordance with OFAC regulations, if it is determined that you or any other person or entity claiming the benefits of any coverage has violated U.S. sanctions law or is a Specially Designated National and Blocked Person, as identified by OFAC, any coverage will be considered a blocked or frozen contract and all provisions of any coverage provided are immediately subject to OFAC. When a surety bond or other form of surety coverage is considered to be such a blocked or frozen contract, no payments nor premium refunds may be made without authorization from OFAC. Other limitations on the premiums and payments may also apply.

Any reproductions are void.
Surety Claims Submission: LexonClaimAdministration@sompo-intl.com
Telephone: 615-553-9500 Mailing Address: Sompo International; 12890 Lebanon Road; Mount Juliet, TN 37122-2870

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Accellence Home Medical Reno MDEG License # (if applicable) MP00074

Physical Address 5450 Mill St. Unit 101

City Reno State NV Zip 89502

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website accellencehomemedical.com

Licensing Company Email jhumphrey@accellencereno.com

Section 2: Personal Information

First Julia Middle Michon Last Humphrey

Alias(es, nicknames, name changes, etc.) Julia Carmichael

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

Mailing Address 5450 Mill St. Unit 101

City Reno State NV Zip 89502

Telephone [redacted] Email jhumphrey@accellencereno.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		2/12 - 5/13	
Address	City	State	Zip
10345 Professional Cr. Suite 200	Reno	NV	89521
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Reno		8/06 - 5/11	
Address	City	State	Zip
1664 N. Virginia St.	Reno	NV	89557
Diploma/Degree obtained, if any			
Social Work			

School Name		From - To (MM/YY – MM/YY)	
Reno High School		9/02 - 6/06	
Address	City	State	Zip
395 Booth St.	Reno	NV	89509
Diploma/Degree obtained, if any			
General			

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

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19 - Curren	[redacted]	Verdi	NV	[redacted]
4/17 - 11/19		Reno	NV	
8/10 - 4/17		Reno	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Accellence Home Medical Reno			From - To (MM/YY – MM/YY): 12/11 - current	
Business Address: 5450 Mill St. Unit 101	City: Reno		State: NV	Zip: 89502
Phone: 775-787-8880	Title: Operations manager		Number of Employed Hours: 24,960	
Description of Duties: manage day to day operations				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/5/24
Date

I, Julia Humphrey, **certify that as the MDEG Administrator for** Accellence Home Medical-Reno,

that I (initial that you have read and meet the following requirements):

1. JH Have a high school diploma or its equivalent;
2. JH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Julia Humphrey
Print Name (First, Last)

Julia Humphrey
Original Signature (electronic, copies or stamps not accepted)

9/5/24
Date

Board Use Only	Date Received: 9/25/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Accellence Home Medical Reno

Pharmacy/Wholesaler License # (if applicable) MP00074

Physical Address 5450 Mill St. Unit 101

City Reno State NV Zip 89502

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email jhumphrey@accellencereno.com

Section 2: Personal Information

First Julia Middle Michon Last Humphrey

Alias(es, nicknames, name changes, etc.) Julia Carmichael

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 5450 Mill St. Unit 101

City Reno State NV Zip 89502

Telephon[redacted] Email jhumphrey@accellencereno.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Phoenix		From - To (MM/YY – MM/YY): 2/12 - 5/13	
Address: 10345 Professional Cr. Suite 200	City: Reno	State: NV	Zip: 89521
Diploma/Degree obtained, if any: MBA			
School Name: University of Nevada Reno		From - To (MM/YY – MM/YY): 8/06 - 5/11	
Address: 16664 N. Virginia St.	City: Reno	State: NV	Zip: 89557
Diploma/Degree obtained, if any: Social Work			
School Name: Reno High School		From - To (MM/YY – MM/YY): 9/02 - 6/06	
Address: 395 Booth St.	City: Reno	State: NV	Zip: 89509
Diploma/Degree obtained, if any: General			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19 - Curre	[redacted]	Verdi	NV	[redacted]
4/17 - 11/19		Reno	NV	
8/10 - 4/17		Reno	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Accellence Home Medical Reno			From - To (MM/YY – MM/YY): 12/11 - Current
Business Address: 5450 Mill St. Unit 101	City: Reno	State: NV	Zip: 89502
Phone: 775-787-8880	Title: Operations Manager		Number of Employed Hours: 24,960
Description of Duties: manage day to day operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Julia Humphrey, **certify that as the designated representative for** Accellence Home Medical-Reno,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JH I am at least 21 years of age;
3. JH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Julia Humphrey
Print Name (First, Last)

Julia Humphrey
Original Signature (electronic, copies or stamps not accepted)

9/5/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Julia Humphrey
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/24
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Julia Humphrey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/25/24
Date

Subscribed and Sworn to before me this 25 day of September, 2024

Lori A Coon
Notary Public Signature

Notary Public State of Nevada
Lori A Coon
My Commission Expires 4/24/2027
Appointment No. 15-1498-12

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Accellence Home Medical Reno
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) MP000074
Physical Address 5450 Mill St. Unit 101
City Reno State NV Zip 89502
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 775-787-8880 Website accellencehomemedical.com
Licensing Company Email jhowitt@nvbell.net

Section 2: Personal Information

First John Middle Robert Last Howitt
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X
Mailing Address 5450 Mill St. Unit 101
City Reno State NV Zip 89502
Telephone [redacted] Email jhowitt@nvbell.net
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California College for Health Sciences		1992-1998	
Address	City	State	Zip
6602 Convoy Ct.	San Diego	CA	92111
Diploma/Degree obtained, if any			
Respiratory therapy			
School Name		From - To (MM/YY – MM/YY)	
Arcadia High School		1976-1978	
Address	City	State	Zip
180 Campus Dr.	Arcadia	CA	91006
Diploma/Degree obtained, if any			
general diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/05-curr [redacted]	[redacted]	Reno	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Accellence Home medical Reno			From - To (MM/YY – MM/YY): 1997 - Current	
Business Address: 5450 Mill St. Unit 101	City: Reno		State: NV	Zip: 89502
Phone: 775-787-8880	Title: Respiratory Therapist / Owner			
Description of Duties: Manage operations and Respiratory patients				

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9.5.2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Hewitt
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-5-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, John Hewitt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-5-2024
Date

Subscribed and Sworn to before me this 5 day of September 2024

Lori a Coon
Notary Public Signature

Notary Public State of Nevada
Lori A Coon
My Commission Expires 4/24/2027
Appointment No. 15-1488-12 (Seal)

Medical Gases, Equipment and Gases (MDEG) Information	
Date Completed:	
MDEG Name:	Accellence Home Medical - Reno
MDEG License #:	MP 000714
MDEG Address:	5450 Mill St #101 Reno, NV 89502
MDEG Telephone #:	775.787.8880
MDEG Fax #:	775.352.9333
MDEG Email:	LAC.coon@accellencereno.com
MDEG Administrator Name:	John Hawitt
MDEG Administrator Start Date:	

List all personnel – (Make copies of this page if additional space is needed)

#	Name (First, Last)	License/Registration # (If applicable)	Position
1	John Hawitt	RC610|18954	owner|RT|ATP
2	Julia Humphrey	ATP 85780	Op mgr|ATP
3	Lori Coon		office manager
4	Tim mitchell		warehouse supervisor
5	Armando martinez		assist warehouse mgr
6	Priscilla Baumeister		marketing
7	Ashleigh Jackson		CSR|biller
8	Jasmin Zavala		CSR
9	Mark Hennicke		CSR|driver
10	Cindy Lancaster		CSR
11	Kassandra Shinkle		Cpap Specialist
12	Roberto Castaneda		Driver
13	Anthony Bundy		Driver
14	Alexis Crozier		Driver
15	Steven Crozier		Driver (last day 9/6/24)
16	Darryn Johnson		Driver
17	Erik West		Driver
18	Gabriel Orozco		warehouse
19	mason garing		warehouse
20	Joshua Reichart		warehouse|driver

Products and Services Provided	Yes	No
Assistive Equipment	✓	
Respiratory Equipment	✓	
Medical Gases	✓	
Life-Sustaining Equipment	✓	
Enteral Services and Equipment		✓
Orthotics and Prosthetics		✓
Stockings		✓
Insulin Pumps		✓

Medical Gases, Equipment and Gases (MDEG) Information	
Date Completed:	9/25/24
MDEG Name:	Accellence Home Medical - Reno
MDEG License #:	MP00074
MDEG Address:	5450 Mill St #101 Reno, NV 89502
MDEG Telephone #:	775 787-8880
MDEG Fax #:	775.352 9333
MDEG Email:	Lacoon@accellencereno.com
MDEG Administrator Name:	John Howitt
MDEG Administrator Start Date:	

List all personnel – (Make copies of this page if additional space is needed)

#	Name (First, Last)	License/Registration # (If applicable)	Position
1	John Howitt	RC610|18954	owner|RT|ATP
2	Julia Humphrey	ATP 85780	Op mgr|ATP
3	Lori Coon		office manager
4	Tim mitchell		warehouse supervisor
5	Armando martinez		assist warehouse mgr
6	Priscilla Baumeister		marketing
7	Ashleigh Jackson		CSR|biller
8	Jasmin Zavala		CSR
9	Mark Hennicke		CSR|driver
10	Cindy Lancaster		CSR
11	Kassandra Shinkle		Cpap Specialist
12	Roberto Castaneda		Driver
13	Anthony Bundy		Driver
14	Alexis (Crozier)		Driver
15	Steven Crozier		Driver (Last day 9/6/24)
16	Darryn Johnson		Driver
17	Erik West		Driver
18	Gabriel Orozco		warehouse
19	Mason Garing		warehouse
20	Joshua Reichart		warehouse|driver

Products and Services Provided	Yes	No
Assistive Equipment	✓	
Respiratory Equipment	✓	
Medical Gases	✓	
Life-Sustaining Equipment	✓	
Enteral Services and Equipment		✓
Orthotics and Prosthetics		✓
Stockings		✓
Insulin Pumps		✓

SOMPO
INTERNATIONAL

NOTICE

U. S. TREASURY DEPARTMENT'S OFFICE OF FOREIGN ASSETS CONTROL (OFAC)

No coverage is provided by this Notice nor can it be construed to replace any provisions of any surety bond or other surety coverage provided.

This Notice provides information concerning possible impact on your surety coverage due to directives issued by OFAC. **Please read this Notice carefully.**

The Office of Foreign Assets Control (OFAC) administers and enforces sanctions policy, based on Presidential declarations of "national emergency". OFAC has identified and listed numerous:

- Foreign agents;
- Front organizations;
- Terrorists;
- Terrorist organizations; and
- Narcotics traffickers;

as "Specially Designated Nationals and Blocked Persons". This list can be located on the United States Treasury's website - http://www.treas.gov/ofac.

In accordance with OFAC regulations, if it is determined that you or any other person or entity claiming the benefits of any coverage has violated U.S. sanctions law or is a Specially Designated National and Blocked Person, as identified by OFAC, any coverage will be considered a blocked or frozen contract and all provisions of any coverage provided are immediately subject to OFAC. When a surety bond or other form of surety coverage is considered to be such a blocked or frozen contract, no payments nor premium refunds may be made without authorization from OFAC. Other limitations on the premiums and payments may also apply.

12890 Lebanon Road Mount Juliet TN 37122 U.S. • Phone: 615.553.9500 • Fax: 615.553.9502

SOMPO INTERNATIONAL

Privacy Notice for Insurance Applicants and Policyholders

At Sompo International we are committed to protecting your personal information and respecting the data protection and privacy rights you have under applicable law and regulations.

When you submit any information to us for the purpose of requesting information from us; about, or obtaining, our products or services; or otherwise, including any personal information, we will use the information in our insurance business to conduct our business and perform our legal obligations, including:

(i) verifying your identity;
(ii) preventing, investigating or reporting fraud or potential fraud, money laundering, terrorism, misrepresentation, security incidents, sanctions violations or any crime, all in accordance with applicable law and regulations;
(iii) assessing, establishing and managing claims and arranging or entering into any appropriate settlements;
(iv) managing, reporting and auditing our business operations;
(v) recovering debt;
(vi) developing, improving and protecting our products, services, website, systems and relationships with you;
(vii) carrying out research, risk management and statistical analyses;
(viii) establishing, exercising or defending legal claims; and
(ix) meeting regulatory and compliance requirements.

With your permission, we may also use your contact details (including email address) to send you information about our products and services or other products and services provided by us or one of our group companies.

We may share your information for the purposes outlined above with:

(i) our group companies;
(ii) brokers, other insurers and underwriters;
(iii) healthcare professionals;
(iv) law enforcement authorities;
(v) other government authorities;
(vi) fraud prevention agencies; and
(vii) third parties involved in any aspect of claims management including surveyors, loss adjusters, claims agents, solicitors and private investigators;
(viii) parties that may have a financial interest in the insurance policy or claim;

(ix) other service providers that may process your personal information on our behalf (for example, IT service providers that host or support our business and may have data that includes your personal information); and

(x) others with your consent or in accordance with applicable law and regulations.

If you have provided information about another person, in doing so you confirm that you have such person's consent to provide the personal information to us, that you have told such person that you have provided the information to us and how we will use the personal information as described in this notice.

To the extent you have provided your consent, and your consent provides the basis for our use of the information, you may withdraw your consent at any time by contacting us as described below.

More details about how we use your personal information may be found on our website at www.sompo- intl.com. The website also provides additional information about your data protection rights, how you may access and update your personal information and other choices you have about how we use your personal information (including how to object to processing or withdrawing your consent at any time). If you have any questions regarding this notice, please contact us at:

Attn: Chief Compliance Officer Sompo International
Waterloo House
100 Pitts Bay Road
Pembroke HM08
Bermuda
Email: Privacy@sompo-intl.com

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03176	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Banner Life Sciences, LLC

Physical Address: 3980 Premier Drive Ste 110

City: High Point State: NC Zip: 27265

Mailing Address (if different from physical address): n/a

City: State: Zip:

Telephone: 336.899.0959 Website: www.bannerls.com

Name of Designated Representative (DR): Tiffany N. Sprague

Licensing Company Email: DR Email: Tiffany.sprague@bannerls.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling ☎ all applicable)
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Legend Pharmaceuticals	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

02/18/25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Patheon Softgels, Inc
Address: 4125 Premier Dr. City: High Point State: NC Zip: 27265
Name: Cardinal Health 105, Inc D/b/a Specialty Pharmaceutical Services
Address: 501 Mason Rd Ste 200 City: La Vernge State: TN Zip: 37086
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware (see attachment A)
Parent Company (if any): Cycle Pharmaceuticals, Inc
Corporation/Organization Name: Banner Life Sciences, LLC
Mailing Address: 3980 Premier Drive Suite 110
City: High Point State: NC Zip: 27265
Telephone: 336.899-0950 Email: tiffany.sprague@bannerls.com
Contact Person Name: Tiffany N. Sprague

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration (See Attachment B (Labeler Code)) 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. (Attachment C)		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** (See Attachment D)	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** (See Attachment A)	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ (See Attachment E)		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/ stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant. (See Attachment F)**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable) (See Attachment G)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Banner Life Sciences, LLC

Facility Name

Tiffany N. Sprague

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

02/18/25

Date

Board Use Only	Date Received: 2/24/25	Amount: $1000 CC ✓

Oparaugo, Marylyn

From: Garikipati, Vandana
Sent: Monday, November 17, 2014 1:47 PM
To: McKinley, Jermaine; Garcia, Claudia; Oparaugo, Marylyn
Subject: FW: Labeler Code Request Approved

FYI, Marylyn will update the team with the next steps to follow and the time frame. Thanks, Vandana

From: edrls@fda.hhs.gov [mailto:edrls@fda.hhs.gov]
Sent: Monday, November 17, 2014 7:00 AM
To: Garikipati, Vandana
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 17-NOV-14
Labeler DUNS: 079579273
Labeler Name: Banner Life Sciences LLC.
Labeler Code: 69387

The Food and Drug Administration (FDA) has assigned the above Labeler Code Number to your firm. The number cannot be used until you have confirmed the assignment. Please resubmit your Labeler Code Request SPL with the assigned number above to confirm the assignment and complete the process. **To do this, open the previous Labeler Code request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new id root and new version number with the original set id root and the appropriate effective time.**

This Labeler Code should be used on all forms related to drug establishment registration and/or drug product listing. Per Title 21, Part 207 of the Code of Federal Regulations (CFR), owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BANNER LIFE SCIENCES LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5599298 8300

SR# 20250483488

Authentication: 202909191

Date: 02-11-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF AUTHORIZATION
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

BANNER LIFE SCIENCES LLC

is a limited liability company formed under the laws of Delaware as Banner Life Sciences LLC and was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on 1st day of November, 2014.

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company has not withdrawn from the State of North Carolina, (ii) the said limited liability company's certificate of authority has not been suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively revoked for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial revocation, withdrawal, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 17th day of February, 2025.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 122247086-1 Reference# 22343050- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

Attachment D

LLC Officer Information

Banner Life Sciences, LLC

3980 Premier Drive, Suite 110

High Point, NC 27265

336.899.0959

FEIN: 47-1819045

No Shares/%ownership issued to Banner Life Sciences LLC officers

Name	**James Harrison**
Title	Group CEO
Address	Broers Building, 21 JJ Thomson Ave, Cambridge, CB3 0FA UK

Name	**Duncan Kennedy**
Title	CFO
Address	Broers Building, 21 JJ Thomson Ave, Cambridge, CB3 0FA UK

Name	**Sarah Gowing**
Title	Group General Counsel and Company Secretary
Address	Broers Building, 21 JJ Thomson Ave, Cambridge, CB3 0FA UK

2025

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1638

LICENSE/CERTIFICATE: **Virtual Manufacturer**
TYPE

Expiration Date **12/31/2025**

LICENSEE OR CERTIFICATOR
BANNER LIFE SCIENCES LLC
3980 PREMIER DRIVE STE 110
HIGH POINT **NC** **27265**

LICENSED
2025
NORTH CAROLINA

Steven W. Troxler

STEVE TROXLER, COMMISSIONER

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

13529949

33539

State of Tennessee
Department of Health

BOARD OF PHARMACY
THIRD PARTY LOGISTICS
CARDINAL HEALTH 105 LLC DBA
SPECIALTY PHARMACEUTICAL SERVICES
501 MASON RD STE 200
LA VERGNE TN 37086

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000005372
EXPIRATION DATE: 08/31/2025

Jennifer L. Rothrock, Esq

2025 State License NC

2025

NOT TRANSFERABLE
STATUTE GS 81.100.110

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1638

LICENSE/CERTIFICATE TYPE: Virtual Manufacturer

Expiration Date: 12/31/2025

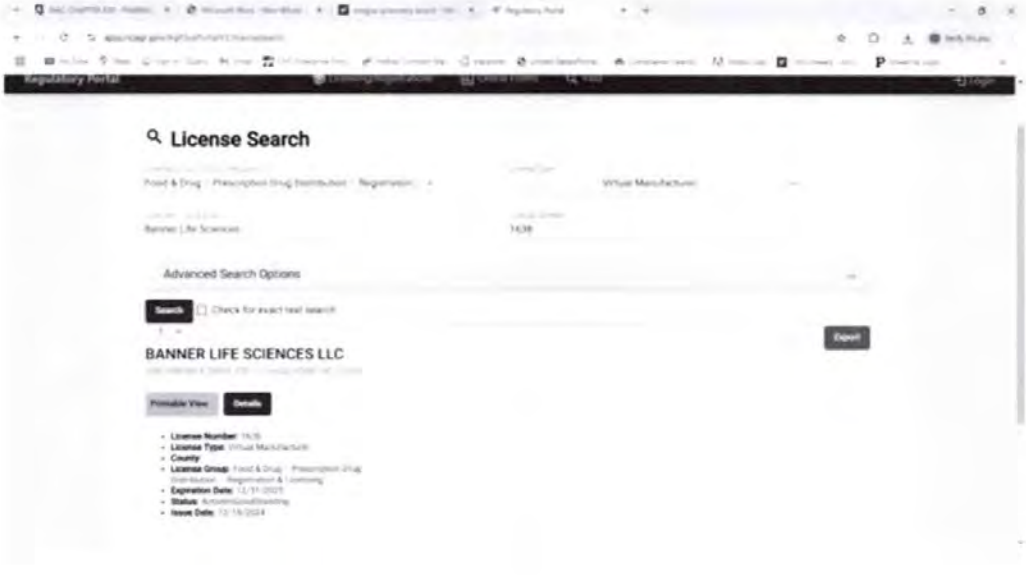
LICENSEE OR CERTIFICATOR: BANNER LIFE SCIENCES LLC
3980 PREMIER DRIVE STE 110
HIGH POINT NC 27265

LICENSED 2025 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

Online Verification



33540

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000005373
EXPIRATION DATE: 08/31/2025

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
THIRD PARTY LOGISTICS
CARDINAL HEALTH 105 LLC DBA

COMMISSIONER OF HEALTH

CYNTHIA RHODES
CARDINAL HEALTH
7000 CARDINAL PLACE
ATTN: QRA
DUBLIN OH 43017

13529920

33540

State of Tennessee
Department of Health

BOARD OF PHARMACY
THIRD PARTY LOGISTICS
CARDINAL HEALTH 105 LLC DBA
SPECIALTY PHARMACEUTICAL SERVICES
15 INGRAM BLVD.
LA VERGNE TN 37086

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000005373
EXPIRATION DATE: 08/31/2025

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Rothauser, Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

0671

DCF171

Attachment H

Nature of Business

Banner Life Sciences LLC (Banner) is a virtual manufacturer that will sell prescription drugs. Banner will utilize a contract manufacturer to produce its products and a licensed third party logistics provider to warehouse and distribute. Accordingly, Banner will never actually physically manufacture or distribute any products at its office space. Provided is contact information for Banner's third party logistics provider and contract manufacturer:

Third Party Logistics Provider:

Cardinal Health 105, Inc. d/b/a Specialty Pharmaceutical Services
15 Ingram Blvd.
La Vergne, TN 37086

Contract Manufacturer:

Patheon Softgels Inc.
4125 Premier Drive
High Point, NC 27265

ASSIGNMENT AND ASSUMPTION AGREEMENT

This ASSIGNMENT AND ASSUMPTION AGREEMENT (this "Agreement"), effective as of January 10, 2025, is entered into by and between Banner Life Sciences Holding, Cooperatief U.A., a cooperative association with exclusion of liability organized under the Laws of the Kingdom of the Netherlands (the "Assignor"), and Cycle Pharmaceuticals, Inc., a Delaware corporation ("Assignee"). The Assignor and Assignee are referred to collectively in this Agreement as the "Parties" and each individually as a "Party." Capitalized terms used and not otherwise defined in this Agreement shall have the respective meanings ascribed to such terms in the Securities Purchase Agreement (as defined below).

RECITALS

WHEREAS, the Assignor is the sole member of Banner Life Sciences, LLC, a Delaware limited liability company (the "Company");

WHEREAS, the Assignor owns all of the limited liability company interests of the Company (the "Shares"); and

WHEREAS, pursuant to that certain Securities Purchase Agreement, dated as of January 10, 2025, by and among Assignor, Assignee and the Company (the "Securities Purchase Agreement"), the Assignor has agreed to sell, convey, assign, transfer and deliver to Assignee, and Assignee has agreed to purchase, acquire, accept and assume from the Assignor, the Shares, subject to the terms and conditions and for the consideration set forth in the Securities Purchase Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the premises and of the mutual promises, representations, warranties, covenants, conditions and agreements contained herein and in the Securities Purchase Agreement, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound by the terms of this Agreement, hereby agree as follows:

1. **Purchase and Assignment**. Effective as of the Closing, and subject to and in accordance with the terms of the Securities Purchase Agreement, (a) Assignor does hereby sell, convey, assign, transfer and deliver to Assignee, and (b) Assignee does hereby purchase, acquire, accept and assume from Assignor, all of Assignor's right, title and interest in and to the Shares, and any and all income, distributions, value, rights, benefits and privileges associated therewith or deriving therefrom accruing on or after the date hereof, in each case, free and clear of all Liens, except for any restriction on transfer pursuant to applicable securities Laws and any Liens thereon created by any action by or on behalf of the Purchaser or any of its Affiliates.

2. **Substitution as Member**. From and after the Closing, Assignee shall be substituted for Assignor as the sole member of the Company, with the right to exercise all rights and powers of a member, and Assignee shall be bound by the provisions of the Limited Liability Company Agreement of the Company, dated as of September 9, 2014 (as may be amended, amended and restated, modified, or supplemented from time to time). Upon the Closing, Assignor shall cease

to be a member of the Company and cease to have or exercise any right or power as a member of the Company. The assignment and transfer of the Shares, the admission of Assignee as a member of the Company and Assignor's ceasing to be a member of the Company will not dissolve the Company, and the Company will continue without dissolution after such assignment and transfer.

3. **Further Assurances**. The Parties agree at their own expense to execute and deliver such further instruments, documents and certificates of transfer and assignment as any other Party may reasonably request to effectively consummate the assignment contemplated herein.

4. **Securities Purchase Agreement**. This Agreement is made and accepted subject to all of the terms, provisions and conditions of the Securities Purchase Agreement. In the event of a conflict between the terms, provisions and conditions of this Agreement and the terms, provisions and conditions of the Securities Purchase Agreement (including as to any matter that is addressed in the Securities Purchase Agreement and not in this Agreement), the terms, provisions and conditions of the Securities Purchase Agreement shall take precedence.

5. **Amendments**. This Agreement may be amended, modified or supplemented only by a written instrument executed by all of the Parties.

6. **Governing Law**. This Agreement shall be governed by and construed in accordance with the internal and substantive Laws of the State of Delaware and without regard to any conflicts of Laws concepts that would apply the substantive Law of some other jurisdiction.

7. **Signatures and Counterparts**. Facsimile or electronic transmission of any signed original document and/or retransmission of any signed facsimile or electronic transmission shall be the same as delivery of an original. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall be considered one and the same agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date and time first above written.

ASSIGNOR:

BANNER LIFE SCIENCES HOLDING, COOPERATIEF U.A.

By: _____

Name: Duncan L. Rennie
Title: Managing Director

By: _____

Name: Jeroen van der Hout
Title: Managing Director

ASSIGNEE:

CYCLE PHARMACEUTICALS, INC.

By: _____
Name:
Title:

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date and time first above written.

ASSIGNOR:

BANNER LIFE SCIENCES HOLDING, COOPERATIEF U.A.

By: _____
Name:
Title:

ASSIGNEE:

CYCLE PHARMACEUTICALS, INC.

By: _____
Name: JAMES HARRISON
Title: DIRECTOR

VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

THIS IS TO CERTIFY that Bond Number 810005465 issued by

Atlantic Specialty Insurance Company, as Surety, dated the 10th

day of June, 2020, in the amount of

Twenty-five Thousand & 00/100 ($ 25,000.00), on behalf

of Banner Life Sciences LLC, as Principal,

and in favor of Nevada State Board of Pharmacy, as Obligee,

covers a term which began on the 10th day of June, 2020,

and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.

Current Renewal Term: 06/10/2024 to 06/10/2025.

Signed, sealed and dated this 6th day of February, 2025.

Atlantic Specialty Insurance Company
Surety

By: Cindy E Johnson
Cindy E. Johnson Attorney-in-Fact

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

intact INSURANCE

Power of Attorney

Surety Bond No: 810005465

Principal Banner Life Sciences LLC
Obligee Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: Cindy E. Johnson each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 6th day of February, 2025

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

intact INSURANCE surety

SURETY BOND SEAL AND DIGITAL SIGNATURE ADDENDUM

ATLANTIC SPECIALTY INSURANCE COMPANY

ATLANTIC SPECIALTY INSURANCE COMPANY ("ASIC") has authorized its respective Attorneys-in-Fact to affix ASIC's corporate seal and digital signature to authorized surety bonds executed on behalf of ASIC by any such Attorney-in-Fact.

This notice verifies a surety bond that is executed on behalf of ASIC by it's Attorney-in-Fact and utilizes the corporate seal below for ASIC shall be deemed to affixed to said bond to the same extent as if its raised corporate seal was physically affixed to the face of the bond. ASIC also hereby agrees that the digital signatures applied to said bond are considered acceptable as if a wet ink signature was physically added to the face of the bond.

Dated this 28th day of July, 2021.

ATLANTIC SPECIALTY INSURANCE COMPANY

For ASIC by: _____

Michael Seff, President Intact Insurance Surety

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Banner Life Sciences LLC

Pharmacy/Wholesaler License # (if applicable) WH03176

Physical Address 3980 Premier Drive Ste 110

City High Point State NC Zip 27265

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 336.899.0959 Website www.bannerls.com

Licensing Company Email _____

Section 2: Personal Information

First Tiffany Middle Nicole Last Sprague

Alias(es, nicknames, name changes, etc.) Nikki

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Greensboro State NC Zip [redacted]

Telephon[redacted] Email tiffany.sprague@bannerls.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida State University		07/04-05/06	
Address	**City**	**State**	**Zip**
600 W College Ave	Tallahassee	FL	32306
Diploma/Degree obtained, if any			
M.Sc Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
University of Virginia		08/00-05/04	
Address	**City**	**State**	**Zip**
P.O. Box 400160, Peabody Hall	Charlottesville	VA	22904
Diploma/Degree obtained, if any			
B.Sc Chemistry, B.A French			

School Name		From - To (MM/YY – MM/YY)	
Princess Anne High School		09/96-06/00	
Address	**City**	**State**	**Zip**
4400 Virginia Beach Blvd	Virginia Beach	VA	23462
Diploma/Degree obtained, if any			
H.S diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/12-current	[redacted]	Greensboro	NC	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Banner Life Sciences (formerly Banner Pharmacaps)			05/08- current	
Business Address		**City**	**State**	**Zip**
3980 Premier Drive Suite 110		High Point	NC	27265
Phone	**Title**		**Number of Employed Hours**	
336-553-8482	VP, Projects and Operations		16 years 9 months	
Description of Duties				
Projects manager for pharma product development, product launch, operations management for commercial production				

Business Name			From - To (MM/YY – MM/YY)	
Azopharma Contract Services			05/06-05/08	
Business Address		**City**	**State**	**Zip**
10320 USA Today Way		Miramar	FL	33025
Phone	**Title**		**Number of Employed Hours**	
954-433-7 480	QC, Scientific Services Manager		2 years	
Description of Duties				
Laboratory testing; management of data review, stability program, and technical reports quality and staff.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

02/18/25
Date

I, Tiffany Nicole Sprague, **certify that as the designated representative for**

Banner Life Sciences, LLC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MS I am at least 21 years of age;
3. MS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tiffany, Sprague

Print Name (First, Last)

Nikki Sprague

Original Signature (electronic, copies or stamps not accepted)

02/18/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Sprague

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Guilford

I, Tiffany Nicole Sprague, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/18/25

Date

Subscribed and Sworn to before me this 18th day of February.

Notary Public Signature

SETH A. MASON NOTARY PUBLIC GUILFORD COUNTY, NC My Commission Expires 04-22-29

(Seal)

Attachment F

2025 Banner Life Sciences, LLC Employees

VP of Regulatory

Thomas Lategan

VP of Projects and Operations

Tiffany (Nicole) Sprague

Chief Financial Officer

Elaina Johnson

Director of Compliance

Kym Creekmore

Medical Marketing Liaison

Leah Bobeck

Medical Science Liaison

Jennifer Slonaker

Medical Science Liaison

Clint Burgess

Corporate Executive Assistant

Phyllis Hardin

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Bridge Global Health

Physical Address: 1 Clay Pl

City: Hapeville State: GA Zip: 30354

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 813-802-9144 Website: www.bridgeglobalhealth.com

Name of Designated Representative (DR): Alexandra Blackwood

Licensing Company Email: jonathans@bridgeglobalhealth.com DR Email: alexb@bridgeglobalhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: IV Solutions	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:
NA

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Grifols International, S.A. Avinguda de la Generalitat,
Address: 152 Parc empresarial Can Sant Joan, City: Barcelona State: Spain Zip: 08174
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Georgia
Parent Company (if any): NA
Corporation/Organization Name: Bridge Global Health, LLC
Mailing Address: 1 Clay Pl
City: Hapeville State: GA Zip: 30354
Telephone: 813-802-9144 Email: jonathans@bridgeglobalhealth.com
Contact Person Name: Jonathan Sharpe

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

	Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
1	• **List of all Officers and Directors.**	✓	✓		
	• **List the top four corporation shareholders and their percent ownership.**	✓			
2	• **List of all corporation shareholders and their percent ownership.**		✓		
	• **List of all partners and their percent ownership.**			✓	
	• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
	• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
	• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
NA	• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
	• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
3	• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
	• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
NA	• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
	• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
	ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
	• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
	• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Bridge Global Health, LLC

Facility Name

Jonathan Sharpe

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/31/2025

Date

Board Use Only	Date Received: 2/3/25	Amount: $1000-CC ✓

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
BRIDGE GLOBAL HEALTH LLC
1 Clay Place
Hapeville, GA 30354
Registration Number: 3021158551
FEI Number*: 3021158551
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
Bridge Global Health LLC[6]
1 Clay Place
Hapeville, GA US 30354
Owner/Operator Number: 10083295[7]

Official Correspondent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA 23666
Phone: 1-757-2240177

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10083295&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10083295&OwnerOperatc

Page Last Updated: 02/03/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10083295&OwnerOperatc

Bridge Global Health, LLC

List of Officers

James Hollowed	President /CEO	100%
Jonathan Sharpe	Chief Operations Officer	0%
Alexandra Blackwood	Designated Representative	0%

1, 2, and 3 from checklist

Control Number : 21160588

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

Bridge Global Health, LLC
a Domestic Limited Liability Company

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 28123522
Date Inc/Auth/Filed	: 06/11/2021
Jurisdiction	: Georgia
Print Date	: 09/17/2024
Form Number	: 211

Brad Raffensperger

Brad Raffensperger
Secretary of State

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005511 Status: Active

Bridge Global Health LLC
1 Clay Place
Hapeville GA 30354

Expires: 06/30/2025
Issued: 02/28/2023

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005511 Status: Active
Bridge Global Health LLC
1 Clay Place
Hapeville GA 30354

Expires: 06/30/2025
Issued: 02/28/2023
Real-time license verification is available at gadch.mylicense.com/verification

Licensee Information

Name: Bridge Global Health LLC

Owner:

DBA:

Address: 1 Clay Place
Hapeville GA 30354

Primary Source License Information

Profession:	Pharmacy	**License No:**	PHWH005511	**License Status:**	Active
License Type:	Wholesaler Pharmacy	**Obtained By Method:**	Application	**License Subtype:**	
Issue Date:	2/28/2023	**Expiration Date:**	6/30/2025	**Last Renewal Date:**	5/10/2023

Discipline Information

- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

No data available

You may close this window to return to your search results

Data current as of: March 19, 2025 9:36:51
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

Georgia Board of Pharmacy

2 Martin Luther King, Jr., Drive, S.E., 11th Floor
East Tower
Atlanta, GA 30334

(404) 651-8000 www.gbp.georgia.gov

Date Mailed: August 13, 2024

Bridge Global Health LLC
1 Clay Place
Hapeville GA 30354

Full Name: Bridge Global Health LLC	Date Issued: 02/28/2023
Type of License: Wholesaler Pharmacy	License #: PHWH005511
Obtained By: Application	Expiration Date: 06/30/2025
License Status: Active	Highest Degree:
Public Board Orders: None	Profession: Pharmacy
Schools:	

VERIFICATION OF LICENSURE

The information above is the only licensure certification information provided by this Division. If other information is needed, it must be obtained from the above-named individual or the agency or institution which initially generated the information. If this verification indicates that a board order exists, please visit our website at https://gadch.mylicense.com/verification/Search.aspx to obtain a copy of the board order.

THE GEORGIA STATE BOARD OF PHARMACY ACT 1881 AMENDED 1889

J. Clinton Joiner
Executive Director
Georgia Board of Pharmacy

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/7/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
3600 American Blvd W Ste 500
Bloomington MN 55431
License#: 0D69293

CONTACT NAME:
PHONE (A/C, No, Ext): 952-358-7500 **FAX (A/C, No):** 952-358-7501
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	
INSURER B : Evanston	
INSURER C : Westchester Surplus Lines Insurance Company	10172
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Bridge Global Health, LLC
1 Clay Place
Atlanta GA 30354
BRIDGLO-02

COVERAGES **CERTIFICATE NUMBER:** 1626382575 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY			BINDER	2/6/2025	2/6/2026	EACH OCCURRENCE	$ 1,000,000
	[X] CLAIMS-MADE [ ] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	[X] POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	[ ] ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	UMBRELLA LIAB [ ] OCCUR			BINDER	2/6/2025	2/6/2026	EACH OCCURRENCE	$ 4,000,000
	[X] EXCESS LIAB [X] CLAIMS-MADE						AGGREGATE	$ 4,000,000
	[ ] DED [ ] RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						[ ] PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A						E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability			BINDER	2/6/2025	2/6/2026	Each Claim	2,000,000
C	Product Recall			BINDER	2/6/2025	2/6/2026	Aggregate Limit	2,000,000 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 108139027

Application/License No. 20210077

Bridge Global Health, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 Clay Place, Hapeville, GA 30354 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, Connecticut 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 22, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of January, 2025.

Bridge Global Health, LLC

Jonathan Sharpe
Digitally signed by Jonathan Sharpe
Date: 2025.01.27 15:57:56 -05'00'
Authorized Representative

Travelers Casualty and Surety Company of America

Christine Lang
Surety Company's Representative

Christine Lang, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Joyce Salt
Witness

Angela Sloan
Witness

Countersigned by:

N/A
Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and the Companies do hereby make, constitute and appoint **CHRISTINE LANG** of **BLOOMINGTON**, **Minnesota**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **16th** day of **February, 2024.**

SEAL SEAL SEAL

State of Connecticut

By: _____
Bryce Grissom, Senior Vice President

City of Hartford ss.

On this the **16th** day of **February, 2024**, before me personally appeared **Bryce Grissom**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

ANNA P. NOWIK NOTARY PUBLIC CONNECTICUT

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-In-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **22nd** day of **January**, **2025**

SEAL SEAL SEAL

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Bridge Global Health LLC MDEG License # (if applicable) NA

Physical Address 1 Clay Pl

City Hapeville State GA Zip 30354

Mailing Address (if different from physical address) SAME

City State Zip

Telephone 678-675-5044 Website bridgeglobalhealth.com

Licensing Company Email alexb@bridgeglobalhealth.com

Section 2: Personal Information

First Alexandra Middle Last Blackwood

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Jonesboro State GA Zip [redacted]

Telephone [redacted] Email alexb@bridgeglobalhealth.com

Are you a citizen of the United States? ☒Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Technical Colleg System of GA		2013	
Address	**City**	**State**	**Zip**
865 Battle Creek Rd	Jonesboro	GA	30236
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2017- Present	[redacted]	Jonesboro	GA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/2015 - 02/2017		Riverdale	GA	
From - To (MM/YY – MM/YY)	[redacted]	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Bridge Global Health			06/2021 - Present
Business Address	**City**	**State**	**Zip**
1 Clay Place	Hapeville	GA	30354
Phone	**Title**	**Number of Employed Hours**	
813-802-9144	Administrative Manager	6,240	
Description of Duties			
Oversight of warehouse ops, implementation of pharmaceutical distribution software (Bluelink ERP), recordkeeping and licensing, inventory management, compliance/regulation			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

NA

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Alexandra Blackwood, **certify that as the MDEG Administrator for**

Bridge Global Health,

that I (initial that you have read and meet the following requirements):

1. AB Have a high school diploma or its equivalent;
2. AB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexandra Blackwood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/10/2025

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bridge Global Health

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1 Clay Place

City Hapeville State GA Zip 30354

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 813-802-9144 Website www.bridgeglobalhealth.com

Licensing Company Email jonathans@bridgeglobalhealth.com

Section 2: Personal Information

First Alexandra Middle _____ Last Blackwood

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Jonesboro State GA Zip [redacted]

Telephone [redacted] Email alexb@bridgeglobalhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Technical College System of GA			2013
Address	**City**	**State**	**Zip**
865 Battle Creek Road	Jonesboro	GA	30236
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2017- Present	[redacted]	Jonesboro	GA	[redacted]
6/2015 - 02/2017		Riverdale	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Bridge Global Health			06/2021-Present	
Business Address		**City**	**State**	**Zip**
1 Clay Place		Hapeville	GA	30354
Phone	**Title**		**Number of Employed Hours**	
813-802-9144	Administrative Manager		6,240	
Description of Duties				
Oversight of warehouse ops, implementation of pharmaceutical distribution software (BlueLink ERP), recordkeeping and licensing, inventory management, compliance/regulation				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Alexandra Blackwood, **certify that as the designated representative for**

Bridge Global Health,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AB I am at least 21 years of age;
3. AB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alexandra Blackwood
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/5/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexandra Blackwood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Butts

I, Alexandra Blackwood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/5/24

Date

Subscribed and Sworn to before me this 5th day of Dec.

Patricia Whittelsey

Notary Public Signature

PATRICIA WHITTELSEY
NOTARY PUBLIC
Butts County, State of Georgia
My Commission Expires 3/26/2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Bridge Global Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1 Clay Pl

City Hapeville State SC Zip 30354

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First James Middle Anthony Last Hollowed

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Lexington State KY Zip [redacted]

Telephone [redacted] Email jimmyh@bridgeglobalhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Georgia College and State University		08/2007-05/2011	
Address	**City**	**State**	**Zip**
231 W. Hancock St	Milledgeville	Ga	31061
Diploma/Degree obtained, if any			
Bachelors of Business Admin			

School Name		From - To (MM/YY – MM/YY)	
Pike County High School		08/2003-05/2007	
Address	**City**	**State**	**Zip**
331 Pirate Dr	Zebulon	Ga	30295
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2014-present	[redacted]	Lexington	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Lisa Ragan Customs Brokerage			08/2011-Present
Business Address	**City**	**State**	**Zip**
1 Clay Place	Hapeville	Ga	30354
Phone	**Title**		
770-996-9903	Vice President of Sales		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

1-27-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Hollowed

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/27/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Clayton

I, James Hollowed, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-27-25

Date

Subscribed and Sworn to before me this 27th day of 2025.

Notary Public Signature

Alexandra Blackwood
NOTARY PUBLIC
Clayton County, GEORGIA
My Commission Expires 03/02/2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Bridge Global Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1 Clay Place

City: Hapeville State: GA Zip: 30354

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 813-802-9144 Website: www.bridgeglobalhealth.com

Licensing Company Email: jonathans@bridgeglobalhealth.com

Section 2: Personal Information

First: Alexandra Middle: Last: Blackwood

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Jonesboro State: GA Zip: [redacted]

Telephone: [redacted] Email: alexb@bridgeglobalhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Technical College System of GA			2013
Address	**City**	**State**	**Zip**
865 Battle Creek Road	Jonesboro	GA	30236
Diploma/Degree obtained, if any			
High School Diploma / GED			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2017- Present	[redacted]	Jonesboro	GA	[redacted]
6/2015 - 02/2017		Riverdale	GA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Bridge Global Health			06/2021-Present
Business Address	**City**	**State**	**Zip**
1 Clay Place	Hapeville	GA	30354
Phone	**Title**		
813-802-9144	Administrative Manager		

Description of Duties

Oversight of warehouse ops, implementation of pharmaceutical distribution software (BlueLink ERP), recordkeeping and licensing, inventory management, compliance/regulation

Business Name			From - To (MM/YY – MM/YY)
LRgistics			05/2020 - Present
Business Address	**City**	**State**	**Zip**
1 Clay Place	Hapeville	GA	30254
Phone	**Title**		
843-696-3042	Ops/Accounting Manager		

Description of Duties

Oversight of warehouse ops, AP/AR Transactions, compliance/regulation, ensuring accurate delivery of invoices, financial statements and reports in a timely manner. Team support for daily operations. Assist with freight paperwork proc

Business Name			From - To (MM/YY – MM/YY)
HWC Logistics			05/2017 - 04/2020
Business Address	**City**	**State**	**Zip**
2929 Roosevelt Hwy,	College Park	GA	30337
Phone	**Title**		
678-705-6002	Account Representative		

Description of Duties

Oversight of warehouse ops, implementation of distribution software management (Ramp ERP), compliance/regulation, account management, processing a high volume of purchase and sales orders daily, inventory control, problem solving.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/5/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexandra Blackwood

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Butts

I, Alexandra Blackwood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/5/24

Date

Subscribed and Sworn to before me this 5th day of Dec.

Patricia Whittelsey

Notary Public Signature

PATRICIA WHITTELSEY
NOTARY PUBLIC
Butts County, State of Georgia
My Commission Expires 3/26/2026
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Bridge Global Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 1 Clay Pl

City: Hapeville State: SC Zip: 30354

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Jonathan Middle: Michael Last: Sharpe

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Greenville State: SC Zip: [redacted]

Telephone: [redacted] Email: jonathans@bridgeglobalhealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Citadel		08/00 - 05/04	
Address	City	State	Zip
171 Moultrie St	Charleston	SC	29409
Diploma/Degree obtained, if any			
Bachelor of Science in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
J.L. Mann High School		08/96 - 05/00	
Address	City	State	Zip
160 Fairforest Way	Greenville	SC	29607
Diploma/Degree obtained, if any			
High Schoiol Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16 - Present	[redacted]	Greenville	SC	[redacted]
08/14 - 07/16		Greenville	SC	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Bridge Global Health			04/23 - Present
Business Address	**City**	**State**	**Zip**
1 Clay Pl	Hapeville	GA	30354
Phone	**Title**		
813-802-9144	COO		

Description of Duties

I deal with all aspects of business operations as Medical Supply and Pharmaceutical Wholesaler.

Business Name			From - To (MM/YY – MM/YY)
Fluor Corporation			12/14 - 03/23
Business Address	**City**	**State**	**Zip**
100 Fluor Daniel Dr	Greenville	SC	29607
Phone	**Title**		
864-281-4400	Project Controls Specialist		

Description of Duties

I managed cost, schedule and progress on multi-billion dollar engineering and construction projects.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Sharpe

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-15-2025

Date

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Greenville

I, Jonathan Sharpe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-15-2025

Date

Subscribed and Sworn to before me this 15 day of January.

Notary Public Signature

RAMI MICHAEL NOTARY PUBLIC MY COMM. EXP. 03/02/2030 SOUTH CAROLINA

(Seal)

Bridge Global Health, LLC

Employees

Perssonnel

James Hollowed	President /CEO	100%
Jonathan Sharpe	COO / Warehouse	0%
Alexandra Blackwood	Designated Representative	0%
Linda Jordan	CFO	
Patty Whitelsey	Accounting	

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	Immediate Parent is not changing - see attached letter	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)
* If making a change, provide current license number: WH 03521		

Section 1: General Information

Facility Name: Catalent Greenville, Inc.

Physical Address: 5440 Martin Luther King Jr Hwy

City: Greenville State: NC Zip: 27834

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 252-752-3800 Website: www.catalent.com

Name of Designated Representative (DR): Troy Woelfel

Licensing Company Email: GMB-CatalentGreenvilleInc@catalent.com DR Email: GMB-CatalentGreenvilleInc@catalent.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Legend Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Manufacturers, Distributors, Repackagers, Clinics and Pharmaceutical Companies		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Catalent Pharma Solutions, Inc.

Corporation/Organization Name: Catalent Pharma Solutions, LLC

Mailing Address: 3031 Red Lion Road

City: Philadelphia State: PA Zip: 19114

Telephone: 732-537-6200 Email: joseph.ferraro@catalent.com

Contact Person Name: Joseph Ferraro

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment B	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment B		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment C	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ DR is not changing.		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment E	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment D	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Greenville, Inc.

Facility Name

Joseph Ferraro

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date 10/24/2024

Board Use Only	Date Received: 11/6/24	Amount: $1000-EC

/ Drug Establishments Current Registration Site (default.cfm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **catalent greenville, inc**

CSVExcel

Filter: Martin Luther King Jr

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
CATALENT GREENVILLE, INC.	3000209735	118814439	MANUFACTURE;	5440 MARTIN LUTHER KING JR BLVD, Greenville, North Carolina (NC) 27834, United States (USA)	12/31/2024

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Tuesday, Jan 2, 2024

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Catalent

Attachment B

Corporate Officer Information

14 Schoolhouse Road
Somerset, NJ 08873
(732) 537 6200

Alessandro Maselli
President & Chief Executive Officer
Ownership: <1%

Ramon J. Ceron
Vice President & Treasurer
Ownership: <1%

Joseph Ferraro
Senior Vice President, General Counsel & Secretary
Ownership: <1%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT GREENVILLE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT GREENVILLE, INC." WAS INCORPORATED ON THE TWENTY-SIXTH DAY OF JULY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6933672 8300

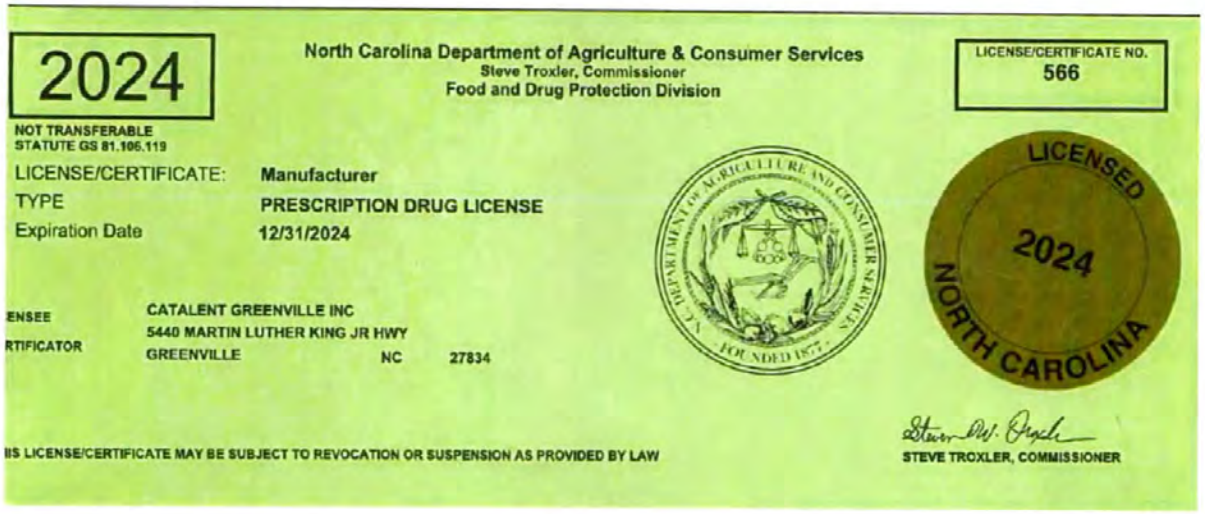
SR# 20241411463

Authentication: 203231565

Date: 04-11-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment D



2024

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
566

LICENSE/CERTIFICATE: Manufacturer
TYPE PRESCRIPTION DRUG LICENSE
Expiration Date 12/31/2024

ENSEE CATALENT GREENVILLE INC
RTIFICATOR 5440 MARTIN LUTHER KING JR HWY
GREENVILLE NC 27834

LICENSED 2024 NORTH CAROLINA

IIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SUR0073955

Application/License No. _____

CATALENT GREENVILLE, INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5440 Martin Luther King Jr Highway Greenville, NC 27834 (Address of Applicant/Principal), as PRINCIPAL, and ARGONAUT INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 469011 San Antonio, TX 78246 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 9, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639 515 and NAC 639 5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639 5937 Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court Payment of any such claim shall be payable to the Nevada State Board of Pharmacy
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of November, 20 22.

APPLICANT/PRINCIPAL
CATALENT GREENVILLE, INC

Authorized Representative

SURETY COMPANY
ARGONAUT INSURANCE COMPANY

Surety Company's Representative

Frances Rodriguez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Halina Kazmierczak

Witness Sandra Diaz

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Argonaut Insurance Company
Deliveries Only: 225 W. Washington, 24th Floor
Chicago, IL 60606
United States Postal Service: P.O. Box 469011, San Antonio, TX 78246
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the Argonaut Insurance Company, a Corporation duly organized and existing under the laws of the State of Illinois and having its principal office in the County of Cook, Illinois does hereby nominate, constitute and appoint:

Sandra Diaz, Debra A Deming, Anne Pottel, Beverly A Woolford, Valorie Spates, Jennifer L Jakaitis, Susan A Welsh, Peter Healy, Nancy Schiree, Akhma Noorhassan, Frances Rodriguez, Francesca Kazmierczak, Kemal Brkanovic

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of

$97,550,000.00

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolution adopted by the Board of Directors of Argonaut Insurance Company:

"RESOLVED, That the President, Senior Vice President, Vice President, Assistant Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the Company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the Argonaut Insurance Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Argonaut Insurance Company has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer on the 19th day of November, 2021

Argonaut Insurance Company

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

by:

Gary E. Grose, President

STATE OF TEXAS
COUNTY OF HARRIS, SS:

On this 19th day of November, 2021 A.D. before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY, to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate Seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force August

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written

KATHLEEN M MEEKS
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07/15/25
NOTARY ID 557902-8

Kathleen M. Meeks

(Notary Public)

I, the undersigned Officer of the Argonaut Insurance Company, Illinois Corporation, do hereby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 9th day of November 2022

ARGONAUT INSURANCE COMPANY CORPORATE SEAL 1948 ILLINOIS

Austin W. King, Secretary

IF YOU HAVE QUESTIONS ON AUTHENTICITY OF THIS DOCUMENT CALL (833) 820 - 9137.

ARGO POWER OF ATTORNEY

FINANCIAL STATEMENT
ARGONAUT INSURANCE COMPANY
STATUTORY BASIS as of 12/31/2021

ASSETS	
CASH & INVESTED ASSETS	$248,880,956
BONDS	$1,181,510,880
STOCKS	$674,977,267
INVESTMENT INCOME DUE AND ACCRUED	$5,760,648
PREMIUM BALANCES	$114,828,986
NET DEFERRED TAX ASSET	$33,875,137
REINSURANCE RECOVERABLE	$92,962,064
OTHER ASSETS	$40,514,092
TOTAL ASSETS	$2,392,360,630

LIABILITIES AND SURPLUS	
UNEARNED PREMIUMS	$304,943,789
LOSSES	$595,583,927
LOSS ADJUSTMENT EXPENSES	$158,243,975
COMMISSIONS	-$4,787,791
TAXES, LICENSES, AND FEES	$10,269,846
OTHER EXPENSES	$9,373,605
FUNDS HELD UNDER REINSURANCE TREATIES	$77,371,315
CURRENT FEDERAL AND FOREIGN INCOME TAXES	$0
REMITTANCES AND ITEMS NOT ALLOCATED	$2,510,048
AMOUNTS WITHHELD/RETAINED BY COMPANY FOR OTHERS	$11,771,696
PAYABLES TO PARENT, SUBSIDIARIES, & AFFILIATES	$52,193,204
PAYABLE FOR SECURITIES	$3,999,489
PROVISION FOR REINSURANCE	$16,445,734
CEDED REINSURANCE PREMIUMS PAYABLE	$47,083,249
OTHER ACCRUED EXPENSES AND LIABILITIES	$1,597,817
TOTAL LIABILITIES	$1,321,201,703
COMMON CAPITAL STOCK	$4,500,000
GROSS PAID IN AND CONTRIBUTED SURPLUS	$525,520,936
UNASSIGNED SURPLUS	$541,137,991
TOTAL SURPLUS TO POLICYHOLDERS	$1,071,158,927
TOTAL LIABILITIES & SURPLUS	$2,392,360,630

Joye Westbrook, being duly sworn, says that he is Head of US Segment Accounting of Argonaut Insurance Company and that to the best of his knowledge, and belief, the foregoing statement is a true and correct statement of the financial condition of said Company as of the 31st of December, 2021.

Subscribed and sworn to before me this 5th day of April 2022

Notary Public

Julian Bandler Westbrook III, Head of US Segment Accounting

CORPORATE SEAL ILLINOIS

Attachment E

As of September 9, 2024

Legal Name - Last Name	Legal Name - First Name
Abreu	Jose
Ackerson	Gregory
Ackerson	Jessica
Allette	Acacia
Allette	Miriam
Alston	Tyrek
Alzer	Fatima
Ambrose	Michael
Anderson	Suzanne
Angol	Bridget
Armistead	William
Arnold	Rebecca
Artuso	Mackenzie
Askew	Timothy
Asmar	Sara
Atkinson	Cenita
Awere	Edward
Ayers	Angela
Babar	Digvijay
Bagley	Francis
Barrios	Alexia
Barry	Lindzie
Barth	Curtis
Basden	William
Bass	Heather
Batts	Charlton
Baxley	Tamatha
Becker	Ryan
Beissner	Brad
Bell	Harry
Bell	Stephanie
Beltran Bejarano	Cristhian
Bernard	Gillian
Berry	Terry
Best	Colene
Bivans	Annabel
Bogard	David
Bordner	Angela
Bowen	James
Bowen	Jeffery
Bowers	Tess
Boyce	Dontre
Boyce	Takiyest
Boyd	Ashley
Branch	Carl
Branch	Carl
Brewer	Brittany
Brewer	Justin
Brewer	Richard
Brewer	Sean
Brickhouse	Wesley
Brower	Mark
Brown	Christian

Brown	James
Brown	Jerry
Brown	Linwood
Brueckner	Amanda
Buck	Ashley
Bullard	Joshua
Bullock	Gerald
Bunn	Haley
Burgos Aguilar	Julio
Burke	Loralea
Bush	Mercedes
Butcher	Katherine
Calvo	William
Cannon	Stephen
Canter	Cathleen
Carmello	Leah
Carney	Deidre
Carrow	Paul
Casteen	Charles
Castor	Morgan
Cherok	Courtney
Chisolm	Ronald
Christie	Shawna
Clark	Louis
Clark	Michael
Clark	Rodney
Clementi	Brendan
Clifton	Hunter
Clipperton	Randall
Coates	Anderson
Cocolas	Harry
Coleman	Jordan
Colon	Richard
Combs	Juliana
Cortes	Brendan
Cortes	Dylan
Cotter	Christie
Coward	Kristin
Cox	Peggy
Credle	Kenneth
Croom	Josh
Crutchfield	Deborah
Cummings	Kasey
Cutler	Harold
Dail	Cynthia
Daly	Debra
Dancy	Debra
Daniels	Jesse
Davenport	Alison
Davis	Bonnie
Davis	David
Day	Chadwick
Decker	Amber
Dickerson	Scott
Dionne	Matthew

Dixon	Alan
Dixon	Brian
Dixon	Lakia
Doetzl	Eric
Donadio	Kyle
Donehoo	Martin
Dowell	Matthew
Ducharme	Jodie
Dunn	Jonathon
East	Julianne
Elicati	Gino
Elks	James
Emory	Stephanie
Euler	Hailey
Evans	Lisa
Ewell	Scott
Fairweather	Haidyn
Faughnan	Caitey
Faulkner	Grayson
Faulkner	Julianne
Felton	Frankie
Figueroa-Landrau	Leslie
Flythe	Adrian
Foster	Milton
Fowler	Kelli
Franklin	Dustin
Freeman	Joseph
French	William
Friend	Scott
Fucci	Megan
Fugit	Kyle
Furlough	Joshua
Gadson Brown	Kyana
Galloway	Joshua
Garcia	Areli
Garcia	Lori
Garcia	Perla
Garcia Reyes	Veronica
Gardner	Franklin
Gardner	Richard
Garrell	Justin
Garrett	Kristi
Garris	Jillia
Gaskins	Janet
Geiger	Micah
Genovese	Steven
Gerdts	Jameson
Gillikin	Justin
Gilmore	Kayla
Ginn	Carolyn
Gladson	Amy
Gladson	David
Godard	John
Godard	Lucas
Godley	Johnny

Godley	William
Gonzalez	Jared
González Mundarain	María
Gooding	Ringo
Grady	Gail
Grant	Charvonna
Gray	Breigh
Gray	Christina
Green	Stacey
Green	William
Green	William
Greene	Phillip
Greer	Thomas
Griffin	Jerry
Griffin	Lillian
Grubich	Nicholas
Grubich	Rachel
Gutierrez Nuno	Jimena
Gutierrez-Nuno	Yessica
Hanley	Sarah
Harper	Delora
Harris	Henry
Harris	Michelle
Harris	Raybon
Hartman	Ashley
Hawkins	Dana
Hayes	John
Heagy	Faith
Heckman	Russell
Henne	Michele
Hill	Joseph
Hinton	Jaron
Hoadley	Sara
Holiday	Latricia
Holzkamm	Rebecka
Honeycutt	Joseph
Hooter	Paul
Hormilla	Maxwell
Horton	Shauna
Howell	Steven
Huff	Thomas
Hunt	Brett
Islam	Marzuq
Israel	William
Jarrett	Kaylynn
Jarrett	Peter
Jefferson	Holly
Jenkins	Austin
Jenkins	Melvin
Johnson	Alexya
Johnson	Kimberly
Jones	Kenneth
Jones	LaToya
Jones	Lauren
Jones	Seth

Joshi	Yogesh
Justice	Caitlin
Kancharla	Joseph Paul
Kelly	Devon
Kettler	Caleb
Khanom	Hafsa
Kiely	Richard
Kiiru	Mercy
King	Nyjir
Kinion	Chase
Kiser	Christopher
Kittrell	William
Knox	Derrick
Lancaster	Madison
Lassiter	Gerald
Latham	Clarence
Lawrence	Kendall
Lawson	Allen
Lawson	Christopher
Leary	David
Lindsay	Rahyanne
Linton	Norman
Lloyd	Justin
Lomas	Karen
Loomis	Thomas
Loshbaugh	Rebecca
Lozano	Erika
Lucarelli	Ariana
Lundergan	James
Lupton	Daniel
Lynch	Jaylin
Lynn	Brandon
Majette	Elizabeth
Mallard	Todd
Mando	Albaraa
Mangiapane	Charles
Marshburn	Timothy
Martens	Christian
Martinez	Angel
Mattheu	Emily
May	Janasia
McAllister	Arica
Mccarter	Mary A
McDaniel	Timothy
McLawhorn	Matthew
Mcneil	Nekeesha
McNeill Jr	John
Meeks	Joseph E
Melton	Andrew
Miles	Kristen
Mills	Amanda
Mills	Blake
Miranda Colon	Zenaida
Mizell	Jerry
Mizelle	Allen

Moore	Rachel
Moore	Zavian
Morris	Patricia
Morris	Teresa
Morrow	Leslie
Mtlaka	Ayanda
Mukadam	Ninad
Neal	Ellis
Neal	Jerry
Nelson	David
Nelson	Gregory
Nelson	Melissa
Nelson	Sonja
Newman	Chivonne
Newton	Austin
Nguyen	Hien
Nicholson	Kameron
Norman	Damon
Norman	Phawn
Norman	Willie
Nowell	Kelaya
Olecki	Danielle
ONeal	Gary
Pannell	Robert
Paramore	William
Parker	Kay
Parrish	Sherry
Pate	Michelle
Pate	Troy
Patel	Aditya
Patel	Monika
Payton	William
Peaden	Jeannette
Perez Chavez	Karen
Perkins	Hudson
Perry	Jacob
Phelps	Brandon
Philbee	Timothy
Phillips	Amber
Phillips	Lauren
Pick	Nicholas
Pietrzak	Jeffrey
Plumley	Zoe
Podruchny	Walter
Pofahl	Walter
Popovich	Anthony
Popovich	Jennifer
Poston	Elizabeth
Preston	William
Price	Gilley
Price	Michael
Proctor	Matthew
Pryor	Sterling
Rambert	Shantez
Rasberry	Rachel

Raynor	Alex
Reaves	Jalisa
Redelman	Stacie
Reichardt	Randi
Reyes	Alba
Rice	Franklin
Richardson	Allison
Riley	Trisha
Rincon	Rosalio
Rios	Nicolas
Rivera Rios	Jonathan
Roberson	Tracey
Rodriguez	Clemente
Rogers	Jeffrey
Rogerson	Becky
Rogerson	Jerry
Rogerson	Michael
Rogerson	Robert
Rose	Jacob
Ross	Jaylin
Ryan	Heather
Sadhale	Yogesh
Sadler	Danny
Sadler	Mallory
Sakowski	Gerald
Saleh	Waleed
Salter	William
Sanchez	Fabricio
Sanford	Monica
Scaggs	Amanda
Scannell	Teisha
Schafer	Kachena
Senanayake	Pasindu
Sesma	Sarabeth
Shanken	Michael
Sheppard	Cheryl
Sheppard	Polina
Sheppard	Vonda
Simonetti	Nicholas
Simpkins	Bradley
Simpson	Julie
Simpson	Lauren
Singleton	Clarence
Singleton	Lewis
Skinner	Tabitha
Smith	Blake
Smith	Christopher
Smith	DeJuan
Smith	Matthew
Smith-Joyner	Annalisa
Sopko	Laura
Soroko	Jacob
Spear	Camron
Spruill	Christopher
Stallings	Rosalyn

Stallings	Steven
Stancill	Wendy
Staton	Jahmari
Steinert	Ralph
Steward	Nicholas
Stocks	Nyasia
Stocks	Tommy
Stox	Merritt
Streeter	Lenora
Styron	Daniel
Suarez	Gracie
Suozzo	Sandra
Suter	Elizabeth
Sutton	Holly
Sutton	Jackie
Sweet	Chris
Szumigala	Craig
Taylor	Tony
Tello Lopez	Zoila
Terry	Crystal
Terry	William
Thai	My
Thereault	Brian
Thomas	Logan
Thota	Shyam Sunder
Tice	Shayna
Tillapaugh	Kimberly
Tolson	Lory
Tomlinson	Abigail
Tripp	William
Tubi	Olaitan
Tucciarone	Patricia
Tuchscherer	Abigail
Tyndall	Karen
Tyree	Jonathan
Tyson	Troy
Vanderburg	Alex
Vaughan	Susan
Vega Piñeiro	Natania
Velazquez	Luis
Victor	Daniel
von Lehmden	Thomas
Wagner	Courtney
Walden	Glenn
Waldrop	Kenneth
Walker	Charles
Ward	Brandon
Warren	Jimmy
Watkins	Gerald
Webb	Daniel
Webb	Erica
Wheatley	Rachel
Whitaker	Hayley
Whitaker	Leticia
Whitaker	Matthew

White	Dylan
White	Gregory
White	Lemont
Whitehurst	Jeffrey
Whitworth	Tenesha
Wiggins	Travis
Wilkes	Brittany
Willer	Nicholas
Willer	Zachary
Williams	Ainsley
Williams	Christopher
Williams	Daniel
Williams	Ronnell
Williams-Dixon	Tonya
Wilson	Ashleigh
Woelfel	Troy
Woolard	Carlton
Woolard	Christopher
Woolard	Marshall
Wurtele	Heather
Yellock	Marc
Zhu	William

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Catalent Pharma Solutions, LLC

Physical Address: 160 S Pharma Drive

City: Morrisville State: NC Zip: 27560

Mailing Address (if different from physical address): Same as physical address.

City: N/A State: N/A Zip: N/A

Telephone: 919-481-4855 Website: www.catalent.com

Name of Designated Representative (DR): Victor Ntoko

Licensing Company Email: GMB-CPSLLC-Morrisville@catalent.com DR Email: victor.ntoko@catalent.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: NDA/ANDA holders		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. - N/A

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Joseph Tanner
Original Signature (electronic, copies or stamps not accepted)

February 03, 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Neurelis, Inc.
Address: 3430 Carmel Mountain Drive, Suite 300 City: San Diego State: CA Zip: 92121

Name: Harm Reduction Therapies
Address: 4800 Montgomery Lane, Suite 400 City: Bethesda State: MD Zip: 20814

Name: N/A
Address: City: State: Zip:

Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A
Date of SEC Registration: N/A SEC Registration Number: N/A Stock Exchange Symbol: N/A

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Catalent Pharma Solutions, Inc.
Corporation/Organization Name: Catalent Pharma Solutions, LLC
Mailing Address: 160 S Pharma Drive
City: Morrisville State: NC Zip: 27560
Telephone: 919-481-4855 Email: GMB-CPSLLC-Morrisville@catalent.com
Contact Person Name: Victor Ntoko

Section 6: Partnership

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Section 7: Sole Owner

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration - See Attachment 1 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. - See Attachment 2		

	Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
	• **List of all Officers and Directors.** See Attachment 3	✓	✓		
N/A	• **List the top four corporation shareholders and their percent ownership.**	✓			
	• **List of all corporation shareholders and their percent ownership.** See Attachment 3		✓		
	• **List of all partners and their percent ownership.**			✓	
	• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment 4	✓	✓	✓	✓
	• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ - See enclosed		✓	✓	✓
	• **Personal History Record Application** must be completed by each shareholder/ stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
	• **Copy of DEA certificate if handling controlled substances** See Attachment 5	✓	✓	✓	✓
	• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
	• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment 6	✓	✓	✓	✓
	• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment 7	✓	✓	✓	✓
N/A	• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ -	✓	✓	✓	✓
N/A	• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
	ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
N/A	• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf. -N/A		✓	✓	✓
N/A	• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Catalent Pharma Solutions, LLC

Facility Name

Joseph Ferraro

Print Name of Authorized Person Submitting Application

Joseph Ferraro

Original signature of Authorized Person (copies or stamps not accepted)

February 03, 2025

Date

Board Use Only	Date Received: 2/10/25	Amount: $1,000 CK 0002038687

An official website of the United States government Here's how you know

FDA

Attachment 1 - FDA Registration

Share | Tweet | Linkedin | Email | Print

Drug Establishments Current Registration Site

New Search

Search Results for *Catalent Pharma Solutions, LLC*

Showing 1 to 1 of 1 entries (filtered from 6 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Catalent Pharma Solutions, LLC	1000110912	119332987	ANALYSIS; MANUFACTURE	160S Pharma Drive, Morrisville, North Carolina (NC) 27560, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Jan 10, 2025

New Search

Attachment 3

Corporation Information

14 Schoolhouse Road
Somerset, NJ 08873
(732) 537-6200

Catalent Pharma Solutions, LLC is a wholly owned subsidiary of Catalent Pharma Solutions, Inc.

Corporate Officers

Alessandro Maselli
President & Chief Executive Officer
<1% Ownership

Ramon J. Ceron
Vice President & Treasurer
<1% Ownership

Joseph Ferraro
Senior Vice President, General Counsel & Secretary
<1% Ownership

Attachment 4

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CATALENT PHARMA SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CATALENT PHARMA SOLUTIONS, LLC" WAS FORMED ON THE FIFTH DAY OF NOVEMBER, A.D. 2003.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3724407 8300

SR# 20250063600

Authentication: 202645002

Date: 01-08-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 7

2025

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
447

LICENSE/CERTIFICATE: **Manufacturer**
TYPE **PRESCRIPTION DRUG LICENSE**
Expiration Date **12/31/2025**

LICENSEE OR CERTIFICATOR
Catalent Pharma Solutions, LLC
160 South Pharma Drive
Morrisville **NC** **27560**

LICENSED 2025 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

North Carolina Department of Agriculture & Consumer Services

Food and Drug - Perscription Drug

Steve Troxler
Commissioner

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita McMullen
Division Director

License Details for Catalent Pharma Solutions, LLC

Licensee Details

Firm Name: Catalent Pharma Solutions, LLC	**License Type:** Manufacturer
Address: 160 South Pharma Drive, Morrisville, NC 27560	**License Number:** 447
License Status: Active – In good standing	**Discipline:** No
Current Issue Date: 1/13/2025	**License Expiration:** 12/31/2025
Original Issue Date: 11/24/2009	

Search URL: https://apps.ncagr.gov/AgRSysPortalV2/licensesearch/fdpd/328927

Attachment 5

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0294556	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4	MANUFACTURER	07-18-2024

CATALENT PHARMA SOLUTIONS, LLC
160 PHARMA DR
MORRISVILLE, NC 275609570

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0294556	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4	MANUFACTURER	07-18-2024

CATALENT PHARMA SOLUTIONS, LLC
160 PHARMA DR
MORRISVILLE, NC 275609570

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0294556	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4	MANUFACTURER	07-18-2024

CATALENT PHARMA SOLUTIONS, LLC
160 PHARMA DR
MORRISVILLE, NC 275609570

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
7285

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SBP150849_002

Application/License No. _____

Catalent Pharma Solutions, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 160 S Pharma Drive, Morrisville, NC 27560 (Address of Applicant/Principal), as PRINCIPAL, and PENNSYLVANIA INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NM (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 10805 Old Mill Road, Omaha, NE 68154 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 14, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 14th day of January, 2025.

APPLICANT/PRINCIPAL
Catalent Pharma Solutions, LLC

Authorized Representative
Joseph Ferraro

SURETY COMPANY
PENNSYLVANIA INSURANCE COMPANY

Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Alisha Riddick

Witness Sharon Monto

SIGNED and SEALED in the presence of:

Witness Dana Donahue

Witness Lori Shelton

Countersigned by:

N/A
Nevada Resident Agent

California Insurance Company · Continental Indemnity Company · Illinois Insurance Company · Pennsylvania Insurance Company

10805 Old Mill Road · Omaha, Nebraska 68154

POWER OF ATTORNEY NO. AONPHI01_0323

KNOW ALL MEN BY THESE PRESENTS: That the California Insurance Company, duly organized and existing under the laws of the State of California and having its principal office in the County of San Mateo, California, and Continental Indemnity Company, Illinois Insurance Company and Pennsylvania Insurance Company, corporations duly organized and existing under the laws of the State of New Mexico and having their principal office in the County of Santa Fe, New Mexico does herby nominate, constitute and appoint:

Patricia A. Rambo, Kimberly G. Sherrod, Cathy H. Ho, Sara Owens, Lori S. Shelton, Dana Donahue, Wayne G. McVaugh, Annmarie Breene, Joanne C.. Wagner, Patricia Dorsaneo, Babette Ward, Patrick Breene

Its true and lawful agent and attorney-in-fact, to make, execute, seal and deliver for and on its behalf as surety, and its act and deed any and all bonds, contracts, agreements of indemnity and other undertakings in suretyship (NOT INCLUDING bonds without a fixed penalty or financial guarantee) provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of:

"Unlimited"

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolution adopted by the Board of Directors of **California Insurance Company, Continental Indemnity Company, Illinois Insurance Company and Pennsylvania Insurance Company.**

"RESOLVED, That the President, Senior Vice President, Vice President, Assisted Vice President, Secretary, Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney of the Company, qualifying the attorney or attorneys named in given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the **California Insurance Company, Continental Indemnity Company, Illinois Insurance Company and Pennsylvania Insurance Company,** all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, **California Insurance Company, Continental Indemnity Company, Illinois Insurance Company and Pennsylvania Insurance Company,** has caused its official seal to be hereunto affixed and these presents to be signed by its duly authorized officer the 16th day of August 2023.

California Insurance Company, Continental Indemnity Company,
Illinois Insurance Company, Pennsylvania Insurance Company

By _____
Jeffrey A. Silver, Secretary

STATE OF NEBRASKA
COUNTY OF DOUGLAS SS:

On this 16th day of August A.D. 2023, before me a Notary Public of the State of Nebraska, in and for the County of Douglas, duly commissioned and qualified, came THE ABOVE OFFICER OF THE COMPANY, to me personally known to be the individual and officer described in, and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, deposed and said that he is the officer of the said Company aforesaid, and that the seal affixed to the preceding instrument is the Corporate Seal of said Company, and the said Corporate seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority and direction of the said corporation, and that Resolution adopted by the Board of Directors of said Company, referred to in the preceding instrument is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Douglas, the day and year first above written.

GENERAL NOTARY - State of Nebraska
LINDA S. DAVIS
My Comm. Exp. September 1, 2027

_____
(Notary Public)

I, the undersigned Officer of the **California Insurance Company,** a California Corporation of Foster City, California, **Continental Indemnity Company, Illinois Insurance Company and Pennsylvania Insurance Company,** New Mexico Corporations of Santa Fe, New Mexico, do herby certify that the original POWER OF ATTORNEY of which the foregoing is full, true and correct copy is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand, and affixed the Seal of said Company, on the 14th day of January , 2025

_____
Jeffrey A. Silver, Secretary

PENNSYLVANIA INSURANCE COMPANY
Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus

Admitted Assets	December 31, 2023	December 31, 2022
Bonds (fair value $3,369,553 and $3,353,283)	$ 3,391,227	$ 3,380,054
Common stocks (cost $20,524,906 and $0)	20,524,906	-
Cash, cash equivalents and short-term investments	44,707,282	32,788,196
Other invested assets (cost $34,373,505 and $39,373,505)	8,511,883	10,376,241
Receivables for securities	-	2,428,000
Cash and invested assets	77,135,298	48,972,491
Premiums receivable, agents' balances and other receivables	19,987,394	14,650,243
Reinsurance recoverable on paid loss and loss adjustment expenses	2,114,711	636,445
Accrued investment income	129,526	119,538
Net deferred tax asset	2,521,454	1,357,198
Guaranty funds receivable or on deposit	109,501	128,818
Receivables from parent, subsidiaries and affiliates	15,220,022	10,408,362
Other assets	16,511,124	21,267,607
Total admitted assets	$ 133,729,030	$ 97,540,702

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss	$ 33,772,111	$ 28,482,789
Reinsurance payable on paid losses and loss adjustment expenses	1,791,205	1,820,403
Loss adjustment expenses	4,659,018	4,752,760
Commissions payable, contingent commissions and other similar charges	119,983	112,810
Other expenses (excluding taxes, licenses and fees)	552,357	300,337
Taxes, licenses and fees (excluding federal and foreign income taxes)	1,348,966	756,166
Current federal and foreign income taxes	1,342,659	1,180,441
Unearned premiums	23,590,244	17,652,210
Ceded reinsurance premiums payable	12,860,415	10,726,449
Remittances and items not allocated	808	3,000
Provision for reinsurance	253,073	414,564
Payable to parent, subsidiaries and affiliates	2,825,457	630,793
Other liabilities	22,276	35,611
Total liabilities	83,138,572	66,868,333
Capital:		
Common capital stock, par value $70 per share; 90,000 shares authorized, issued and outstanding	6,300,000	6,300,000
Surplus:		
Gross paid in and contributed surplus	61,128,848	30,578,480
Unassigned funds (surplus)	(16,838,390)	(6,206,111)
Total surplus	44,290,458	24,372,369
Total capital and surplus	50,590,458	30,672,369
Total liabilities and capital and surplus	$ 133,729,030	$ 97,540,702

The undersigned, being duly sworn, says: That he is the Senior Vice President of Pennsylvania Insurance Company; that said Company is a corporation duly organized in the state of New Mexico, and licensed and engaged in the State of New Mexico and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of his knowledge and belief the above statement is a full, true and correct statement of.

Robert Stafford, Senior Vice President

Attest:

General Notary - State of Nebraska
AMY C. SINGLETON
My Comm. Exp. Oct. 18, 2024

Sworn to before me this 29 day of February 2024.

Amy C. Singleton, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Catalent Pharma Solutions, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 160 S Pharma Drive

City: Morrisville State: NC Zip: 27560

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 919-481-4855 Website: www.catalent.com

Licensing Company Email: GMB-CPSLLC-Morrisville@catalent.com

Section 2: Personal Information

First: Victor Middle: Ndile Last: Ntoko

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Cary State: NC Zip: [redacted]

Telephone: 919-481-4855 Email: GMB-CPSLLC-Morrisville@catalent.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Alabama Huntsville		08/15 - 05/17	
Address	**City**	**State**	**Zip**
301 Sparkman Drive	Huntsville	AL	35899
Diploma/Degree obtained, if any			
Certification in Supply Chain Management			

School Name		From - To (MM/YY – MM/YY)	
University of Alabama Huntsville		08/11 - 05/15	
Address	**City**	**State**	**Zip**
301 Sparkman Drive	Huntsville	AL	35899
Diploma/Degree obtained, if any			
Masters in Business Administration (MBA) with concentration in Supply Chain Management			

School Name		From - To (MM/YY – MM/YY)	
University of Buea		09/01 - 12/04	
Address	**City**	**State**	**Zip**
Buea South West Region, Cameroon, P.O Box 63		Cameroo	N/A
Diploma/Degree obtained, if any			
Bachelor of Science in Environmental Science with a minor in Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Government High School		09/99 - 06/01	
Address	**City**	**State**	**Zip**
Limbe, South West Region, Cameron	N/A	N/A	N/A
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/18 -Present	[redacted]	Cary	NC	[redacted]
10/99 - 04/18		Madison	AL	
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Catalent Pharma Solutions, LLC			03/18- Current	
Business Address		**City**	**State**	**Zip**
160 S Pharma Drive		Morrisville	NC	27560
Phone	**Title**		**Number of Employed Hours**	
919-481-4855	Director, Quality / Interim Director Supply Chain		14,018	
Description of Duties				
Responsible for directing quality operations for analytical testing, providing oversight for R&D, clinical and commercial manufacturing. Partnered with Global Procurement to optimize inventory and working capital.				

Business Name			From - To (MM/YY – MM/YY)	
Par Pharmaceuticals/Qualitest Pharmaceuticals			04/08-03/18	
Business Address		**City**	**State**	**Zip**
130 Vintage Drive NE		Huntsville	AL	35811
Phone	**Title**		**Number of Employed Hours**	
N/A -no longer an active company	Sr. Manager/ Manager/Associate Director, Quality		20,500	
Description of Duties				
Coordinated and collaborated with other quality, engineering, supply chain and manufacturing operations functions to implement improvement and ensure quality standards are in place.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided. N/A

This is in response to Question # N/A. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

04 Feb 2025
Date

I, Victor Ntoko, **certify that as the designated representative for**

Catalent Pharma Solutions, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VNN I am at least 21 years of age;
3. VNN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VNN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VNN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VNN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VNN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Victor Ntoko

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04Feb2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Victor Ntoko

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04 Feb 2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Michaela N Wilson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04 Feb 2025

Date

Subscribed and Sworn to before me this 4th day of February 2025

Notary Public Signature

MICHAELA N. WILSON NOTARY PUBLIC WAKE COUNTY, NC

(Seal)

Attachment 6 - Employee List

First	Last
Harrison	Beck
Anjali	Beniwal
Amanda	Berry
Daniel	Briggs
Jeremy	Brooks
Danielle	Ester
Gannon	Griffin
Amr	Hefnawy
Thomas	Henry
Amy	Hill
Theresa	Isbell
Sung	Kang
Christopher	Kloc
Jerry	Lopez Sanchez
Ryan	McGirt
Matthew	Owen
Tyler	Parker
Komalben	Patel
Colin	Patrick
Blake	Poe
Brittany	Przybyl
Monaca	Richardson
Michael	Smalley
Kathryn	Szarek
Gabriella	Villalon
Cornelius	Williams
Michael	Wolfe
Emmet	Wood
Daniel	Young
Kimberly	Johnson
Leslie	Jones

Attachment 6 - Employee List

First	Last
MacKenzie	Telesco
Marcy	Wylie
Christopher	Moore
Cara	Breeden
Neha	Deshpande
Navdeep	Malkar
Kimberly	Weitkamp
Pamela	Keith
David	Wilcox
Malinda	Batts
Laxmi	Dahal
Cedric	Poston
Natasha	Artis
Qua'Diesha	Battle
Christopher	Cordero

Attachment 5 - Employee List

First	Last
Dinesh	Ghimire
William	Graddy
Priscilla	Green
Michael	Kirby
Kyle	Leslie
Dwuan	Martin Jr
Kristopher	McCall
Raheim	McCoy
Latochia	McIntyre
Kent	Miles
Deshaun	Mitchell
Larry	Morgan
Darius	Pittman
Elizabeth	Roberson
Amjad	Saleem
Lauren	Stinson
Vicky	Surles
Travis	Watson
Cory	White
Sonya	Williams
Shannon	Youmans
Tyler	Bailey
Ebou	Kah
Kenneth	Lody
April	Penzabene
Arthur	Wall
William	Wiedmann
Victor	Ntoko
Tavoris	Rogers
Stephanie	Laird
James	Melville

Attachment 6 - Employee List

First	Last
Michael	Taylor
Barbara	Clark
Robin	Hutt
Michelle	Otte
Shane	Hoover
Angela	Daughety
Mollie	Piron
Joshua	Smith
Alexander	Spears
Christopher	Yang
Amanda	Geller-Carrillo
Sean	Jacob
AunQuanetta	McGee
Aurora	Nieves-Aponte
Troy	Connolly
Hai	Le
Anthony	Eatman
Scott	Hudson

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Granulation Technology, Inc.

Physical Address: 12 Industrial Road

City: Fairfield State: NJ Zip: 07004

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 973-276-0740 Website: https://granulationtech.com/

Name of Designated Representative (DR): Amit Nigalaye

Licensing Company Email: Amit@granulationtech.com DR Email: Amit@granulationtech.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

None

Original Signature (electronic, copies or stamps not accepted)

9/25/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Products currently not distributing to NV

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): _____

Corporation/Organization Name: Granulation Technology, Inc.

Mailing Address: 12 Industrial Road

City: Fairfield State: NJ Zip: 07004

Telephone: 973-276-0740 Email: Amit@granulationtech.com

Contact Person Name: Amit Nigalaye

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Granulation Technology, Inc.

Facility Name

AMIT NIGALAYE

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/25/24

Date

Board Use Only	Date Received: 9/30/24	Amount: $1000-ck 2210

An official website of the United States government Here's how you know

FDA

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Drug Establishments Current Registration Site

New Search

Search Results for *Granulation Technology, Inc.*

Showing 1 to 1 of 1 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
GRANULATION TECHNOLOGY, INC.	3001236066	847132193	MANUFACTURE	12 Industrial Road, FAIRFIELD, New Jersey (NJ) 07004, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Mar 07, 2025

New Search

Granulation Technology, Inc.
12 Industrial Road, Fairfield, NJ 07004 Ph.: (973) 276-0740 Fax: (973) 276-0741

A list of officers
Granulation Technology, Inc.

S. No	Name	Ownership Information
1	Amit Nigalaye	President and Owner
2	Mitali Kulkarni	Regulatory Affairs & Quality Control
3	Kinnesh Patel	Manufacturing & Packaging
4	Raguraman Vekata Krishnan	Quality Control

Printed Name: AMIT NIGALAYE
Signature:
Date: 9/25/24

Granulation Technology, Inc.
12 Industrial Road, Fairfield, NJ 07004 Ph.: (973) 276-0740 Fax: (973) 276-0741

Ownership Information

Granulation Technology, Inc.

Name: Amit Nigalaye

Ownership Information: President and Owner

Phone #: 973-276-0740

Address: 12 Industrial Rd, Fairfield, NJ 07004.

% Of Ownership: 100%

Printed Name: AMIT NIGALAYE

Signature:

Date: 9/25/24

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH CHARTER DOCUMENTS

GRANULATION TECHNOLOGY, INC.
0100706254

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 6th day of October, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6157764382

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH CHARTER DOCUMENTS

GRANULATION TECHNOLOGY, INC.
0100706254

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on May 15, 1997.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

AMIT NIGALAYE
12-14 INDUSTRIAL ROAD
FAIRFIELD, NJ 07004

I further certify that as of the date of this certificate, the following amendments and changes are on file in this office:

REVOKED FOR FAILURE TO PAY ANNUAL REPORTS	*12/16/2013*
Annual Report Filing with address change	*06/08/2014*
REINSTATEMENT PROCESS PENDING	*06/08/2014*
CHANGE OF AGENT AND OFFICE	*06/09/2014*
REINSTATED (ANNUAL REPORTS)	*06/16/2014*
Annual Report filing with officer/member change	*03/13/2017*
CHANGE OF AGENT AND OFFICE	*05/08/2018*
Annual Report filing with officer/member change	*03/04/2020*

Continued on next page...

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0752233

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [ ] wholesaler which conducts business at the following locations in this State:

12 INDUSTRIAL RD FAIRFIELD, NJ 07004-

Reg. No.
5002578

GRANULATION TECHNOLOGY, INC.
12 INDUSTRIAL RD
FAIRFIELD, NJ 07004-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0437360	09-30-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	08-05-2024

GRANULATION TECHNOLOGY, INC.
12 INDUSTRIAL RD
FAIRFIELD, NJ 070043018

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0437360	09-30-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	08-05-2024

GRANULATION TECHNOLOGY, INC.
12 INDUSTRIAL RD
FAIRFIELD, NJ 070043018

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0437360	09-30-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5,L1	MANUFACTURER	08-05-2024

GRANULATION TECHNOLOGY, INC.
12 INDUSTRIAL RD
FAIRFIELD, NJ 070043018

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
9300 9333 7285 1228 1100 8112 9143 9050

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 812625

Application/License No. _____

GRANULATION TECHNOLOGY INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 12 INDUSTRIAL RD FAIRFIELD, NJ 07004 (Address of Applicant/Principal), as PRINCIPAL, and HUDSON INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of DELAWARE (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 8777 N. GAINEY CENTER DRIVE STE 240 SCOTTSDALE, AZ 85258 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on SEPTEMBER 9, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 202

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9TH day of SEPTEMBER, 2024.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

JADE A WHITTLE
Notary Public, State of New Jersey
My Commission Expires Jan 19, 2027

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Not Needed
Nevada Resident Agent

Posted February 20, 2020

HUDSON
INSURANCE GROUP

Bond Number: 812625

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

of the State of South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

Twenty Five Thousand And 00/100 Dollars ($25,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly d, on this 2nd day of June, 20 22 at New York, New York.

: seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY
NOTARY PUBLIC
STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 9th day of September, 2024.

(Corporate seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Granulation Technology, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 12 Industrial Road

City: Fairfield State: NJ Zip: 07004

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 973-276-0740 Website: https://granulationtech.com/

Licensing Company Email: Amit@granulationtech.com

Section 2: Personal Information

First: Amit Middle: Ashok Last: Nigalaye

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Wayne State: NJ Zip: [redacted]

Telephone: [redacted] Email: Amit@granulationtech.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Boston University		09/2007-05/2011	
Address	**City**	**State**	**Zip**
233 Bay State Road	Boston	MA	02215
Diploma/Degree obtained, if any			
BSc			

School Name		From - To (MM/YY – MM/YY)	
Wayne Hills high School		09/2003-06/2007	
Address	**City**	**State**	**Zip**
272 Berdan Ave	Wayne	NJ	07470
Diploma/Degree obtained, if any			
High school			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2001-present	[redacted]	Wayne	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Granulation Technology, Inc				From - To (MM/YY – MM/YY): 01/2017-Present
Business Address: 12 Industrial Road		City: Fairfield	State: NJ	Zip: 07004
Phone: 973-276-0740	Title: President			Number of Employed Hours: 15840
Description of Duties: See attached				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Granulation Technology, Inc.
12 Industrial Road, Fairfield, NJ 07004 [redacted]

Description of Duties of Designated Representative (DR)

- Governing the finances of the corporation. Deciding which business opportunities and capital projects to invest company funds based on calculations and projections.
- Establishing new lines of business. Making the transition from a CMO business to generic pharmaceutical business. Negotiating supply agreements with clientele and pricing with vendors.
- Communicating with R&D and Regulatory department heads on new product development and compliance.
- Managing and directing Quality and Production department heads in GMP meetings.
- Full-time managerial or supervisory experience in a wholesale distribution and the record keeping related to prescription drugs.
- Aware of 21 CFR, Federal Food, Drug and Cosmetic Act, DEA and its supporting regulations.
- Managing the administrative and executive aspects including team building, performance evaluation, and company growth.

Printed Name: AMIT NIGALAYE
Signature:
Date: 9/25/24

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

None

Original Signature (electronic, copies or stamps not accepted)

9/25/24
Date

I, AMIT NIGALAYE, **certify that as the designated representative for**

Granulation Technology, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

AMIT NIGALAYE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AMIT NIGALAYE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Essex

I, Amit Nigalaye, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/25/24

Date

Subscribed and Sworn to before me this 25 day of September 2024

Notary Public Signature

CHRISTIANA R OGUJE
Notary Public - State of New Jersey
My Commission Expires Jan 14, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Granulation Technology, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 12 Industrial Road

City: Fairfield State: NJ Zip: 07004

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 973-276-0740 Website: https://granulationtech.com/

Licensing Company Email: Amit@granulationtech.com

Section 2: Personal Information

First: Amit Middle: Ashok Last: Nigalaye

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Wayne State: NJ Zip: [redacted]

Telephone: [redacted] Email: Amit@granulationtech.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Boston University			09/2007-05/2011
Address	**City**	**State**	**Zip**
233 Bay State Road	Boston	MA	02215
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Wayne Hills high School			09/2003-06/2007
Address	**City**	**State**	**Zip**
272 Berdan Ave	Wayne	NJ	07470
Diploma/Degree obtained, if any			
High school			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2001-present	[redacted]	Wayne	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Granulation Technology, Inc			01/2017-Present	
Business Address		**City**	**State**	**Zip**
12 Industrial Road		Fairfield	NJ	07004
Phone	**Title**			
973-276-0740	President			
Description of Duties				
See attached				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

none

Original Signature (electronic, copies or stamps not accepted)

9/25/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AMIT NIGALAYE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Essex

I, Amit Nigalaye, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/25/24

Date

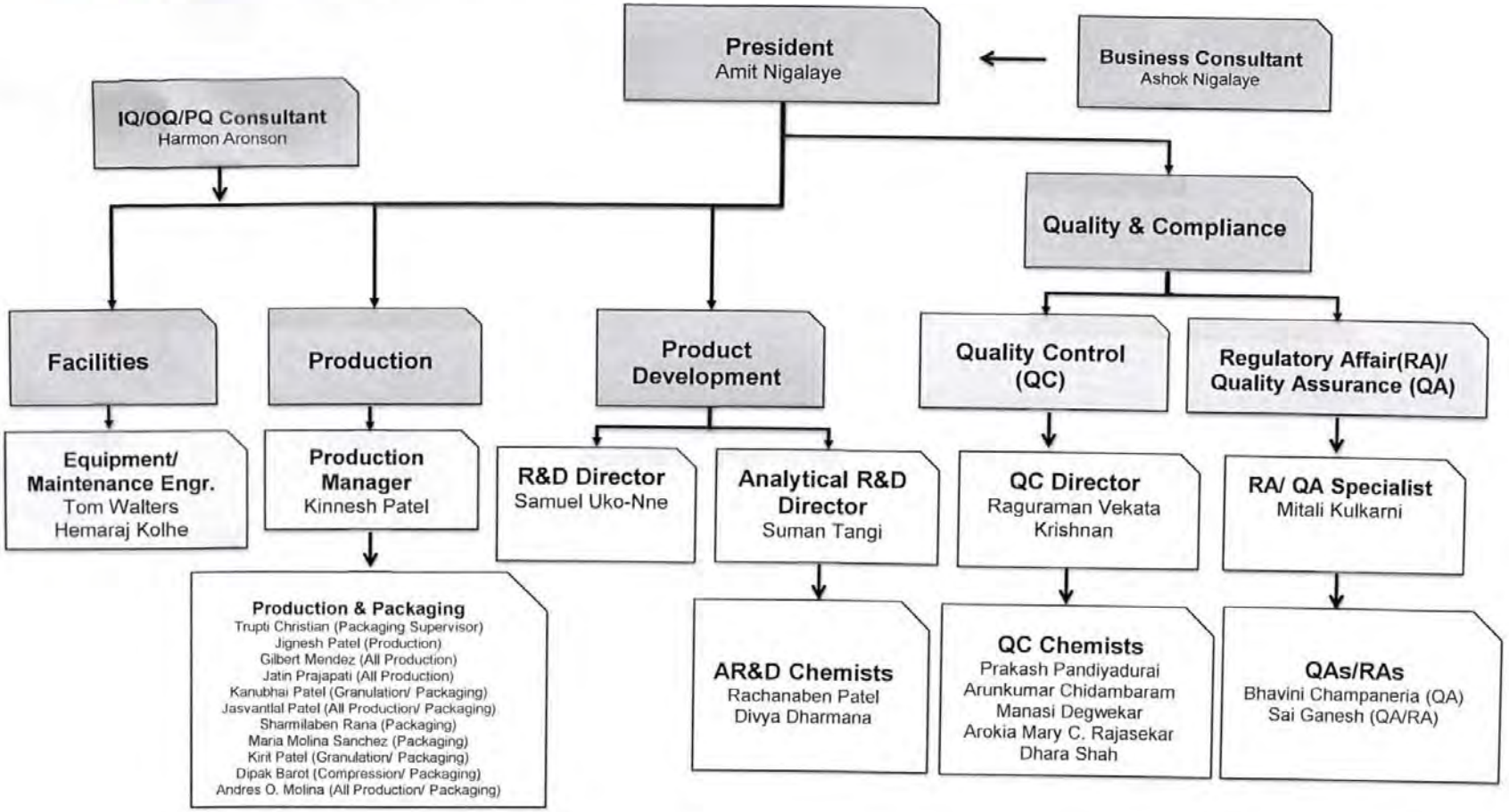
Subscribed and Sworn to before me this 25 day of September, 2024

Notary Public Signature

CHRISTIANA R OGUJE
Notary Public - State of New Jersey
My Commission Expires Jan 14, 2025

(Seal)

GRANULATION TECHNOLOGY, INC.
ORGANIZATION CHART 2025



Mitali Kulkarni

Printed On: 3/4/2025

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Nuclein, LLC

Physical Address: 500 Center Ridge Dr, Ste 400

City: Austin State: TX Zip: 78753

Mailing Address (if different from physical address): 8305 Cross Park Dr

City: Austin State: TX Zip: 78754

Telephone: 512-354-7242 Website: https://nuclein.com

Name of Designated Representative (DR): Jeffrey Stukuls

Licensing Company Email: jeffrey@nuclein.com DR Email: jeffrey@nuclein.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Nuclein, LLC

Mailing Address: 8305 Cross Park Dr

City: Austin State: TX Zip: 78754

Telephone: 512-354-7242 Email: jeffrey@nuclein.com

Contact Person Name: Jeffrey Stukuls, CFO

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Org Chart	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nuclein, LLC

Facility Name

Jeffrey Stukuls, CFO

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/31/2025

Date

Board Use Only	Date Received: 2/10/25	Amount: $1000-CK 3015

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
Nuclein, LLC
500 Center Ridge Dr Ste 400
Austin, TX 78753
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2025

Owner/Operator:
Nuclein, LLC
8305 Cross Park Drive
Austin, TX US 78754
Owner/Operator Number: 10092415

Official Correspondent:
Chelynne Lee
8305 Cross Park Drive
Austin, TX 78754
Phone: 1-512-6493026

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 01/06/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Nuclein

January 31, 2025

Nuclein, LLC List of Officers

Alan R. Blake
Chief Executive Officer
Email: alan@nuclein.com
[redacted]

Jeffrey A. Stukuls
Chief Financial Officer
Email: jeffrey@nuclein.com
Phone: [redacted]

Nuclein, LLC List of Directors

Dr. William Cunnigham, Chairman
Alan Blake
Dr. John Butler
Sanjay Chandra
Richard Crockett, MD
David Shockley, Jr.
Walter Narajowski

Nuclein

January 31, 2025

Nuclein, LLC List Shareholders

Alan Blake	13.9%
Richard Crockett	13.1%
Chandra Family Holdings, LTD.	4.6%
JSRGB Trust	4.5%
TPEG Nuclein QP Investors LLC	9.8%
Trinity Nuclein Rd II QP Investors LLC	7.3%
Jack W. Schuler Living Trust	3.4%
80+ individual <3% holders	40.2%
Options Holders	3.2%
TOTAL	**100.0%**

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Nuclein, LLC (file number 802732913), a Domestic Limited Liability Company (LLC), was filed in this office on May 26, 2017.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on January 30, 2025.

Jane Nelson
Secretary of State

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/medical-device-manufacturers-distributors**.
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

NUCLEIN LLC
8305 CROSS PARK DR
AUSTIN TX 78754

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

NUCLEIN LLC

500 CENTER RIDGE DR STE 400
AUSTIN, TX 78753

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1003543
Expires: October 22, 2026

NON-TRANSFERABLE

Commissioner

514654

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

January 28, 2025

Jeffrey Stukuls
Nuclein
jeffrey@nuclein.com

CFN: 2122247
Lic.: 1003543
Type: 2503
File: 9014

Re: License Verification

Dear Jeffrey Stukuls:

This letter shall serve as a verification of licensure for the following firm:
NUCLEIN LLC
500 CENTER RIDGE DR, STE 400
AUSTIN, TX 78753

License No.	1003543
Type of license:	Device Manufacturer
Status of license:	Current
Date license issued:	11/01/2024
Date license expires:	10/22/2026
Disciplinary action:	None

The firm is in good standing as of the date of this letter. *This firm has not been inspected. The Department's inspection policy prioritizes inspections based on risk and availability of inspectors. *

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/12/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Watkins Insurance Group - Marble Falls P.O. Box 280 Marble Falls TX 78654	CONTACT NAME: Misty Hernandez PHONE (A/C, No, Ext): 830-693-3541 FAX (A/C, No): 830-693-2521 E-MAIL ADDRESS: mhernandez@watkinsinsurancegroup.com
INSURED NUCLE-1 Nuclein, LLC 8305 Cross Park Drive Austin TX 78754	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Continental Casualty Company — 20443 INSURER B : The Continental Insurance Company — 35289 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 501067173 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			6045325032	6/21/2024	6/21/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ 0 $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			6045325032	6/21/2024	6/21/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 10,000			6045325080	6/21/2024	6/21/2025	EACH OCCURRENCE AGGREGATE $	$ 4,000,000 $ 4,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? Y/N [ ] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		6050333421	6/21/2024	6/21/2025	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A	Property Special Form, RC			6045325032	6/21/2024	6/21/2025	Contents Deductible	7,700,000 2,500

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Commercial GL Products & Completed Operations:
Hudson Excess Insurance Company HPC1001308 01 Effective 02/05/2025-02/05/2026 Limits $5,000,000 Per Occurrence $5,000,000 Aggregate
Retro Dates: Limit $2,000,000/$2,000,000 Effective 01/14/2022
Retro Dates: Limit $5,000,000/$5,000,000 Effective 02/05/2025
Location: 500 Center Ridge Drive Suite 400, Austin, TX 78753
Additional Insureds: Tech Ridge Associates (3.2 and 3.3) LLC and Live Oak-Real Estate are additional insured's as their interest may appear. 30 day notice of cancellation endorsement applies when required by written contract.

CERTIFICATE HOLDER

Tech Ridge Associates (3.2 and 3.3) LLC and
Live Oak Real Estate
2725 Bee Cave Road
Austin TX 78747

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Patrick L. Watkins

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CNA

Commercial Umbrella

Renewal Declaration

POLICY NUMBER
B 6045325080

COVERAGE PROVIDED BY
CONTINENTAL CASUALTY COMPANY
151 N Franklin
CHICAGO, IL 60606

FROM - POLICY PERIOD - TO
06/21/2024 06/21/2025

INSURED NAME AND ADDRESS
NUCLEIN, LLC
7301 N FM 620 RD STE 155-113
AUSTIN, TX 78726-4539

AGENCY NUMBER
044573

AGENCY NAME AND ADDRESS
WATKINS INSURANCE GROUP
2100 N US HIGHWAY 28
PO BOX 280
MARBLE FALLS, TX 78654
Phone Number: (830)693-4391

BRANCH NUMBER
763

BRANCH NAME AND ADDRESS
AUSTIN BRANCH
300
9442 N CAPITAL OF TEXAS HWY
AUSTIN, TX 78759
Phone Number: (512)502-6400

This policy becomes effective and expires at 12:01 A.M. standard time at your mailing address on the dates shown above.

The Named Insured is a Limited Liability Company

Your policy is composed of this Declarations, with the attached Coverage Forms, and Endorsements if any. The Policy Forms and Endorsement Schedule shows all forms applicable to this policy at the time of policy issuance.

PREMIUM

Premium Basis	Estimated Exposure	Rate	Estimated Advance Premium
Flat Charge			$1,616

Minimum Premium: $1,616 Annual Total Advance Premium: $1,616.00

Your Premium includes the following amount for
Certified Acts of Terrorism Coverage $16.00

Audit Period is Not Auditable

POLICY NUMBER
B 6045325080

INSURED NAME AND ADDRESS
NUCLEIN, LLC
7301 N FM 620 RD STE 155-113
AUSTIN, TX 78726-4539

POLICY LIMITS OF INSURANCE

Each Incident: $4,000,000 Aggregate: $4,000,000

RETAINED LIMIT

Retained Limit: $10,000

SCHEDULE OF UNDERLYING INSURANCE

Underlying Insurer Policy Number Policy Period	Underlying Insurance	Coverages	LimitS of Insurance
Transportation Insurance Co. 6045325032 Eff: 06/21/2024 to 06/21/2025	General Liability	Each Occurrence Limit General Aggregate Limit Applies per location Doesnt apply per project Products/Completed Operations Aggregate Limit Personal and Advertising Injury Liability Limit	$1,000,000 $2,000,000 $EXCLUDED $1,000,000
Transportation Insurance Co. 6045325032 Eff: 06/21/2024 to 06/21/2025	Automobile Liability	Combined Bodily Injury and Property Damage Liability: Each Accident Limit ----------or---------- Bodily Injury Liability: Each Person Limit Each Accident Limit Property Damage Liability: Each Accident Limit	 $1,000,000 ---------- $ $ $
Continental Insurance Company 6050333421 Eff: 06/21/2024 to 06/21/2025	Employers Liability	Bodily Injury By Accident: Each Accident Limit Bodily Injury By Disease: Each Employee Limit Policy Limit	 $1,000,000 $1,000,000 $1,000,000

In any jurisdiction, state, or province where the amount of Employers Liability Insurance provided by the Underlying Insurer(s) is by law "Unlimited", the underlying Employers Liability limit(s) shown in the above schedule do not apply and no coverage shall be provided for Employers Liability under this policy.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101390917

Application/License No. oplying and need this insura

Nuclein, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 500 Center Ridge Dr, Ste 400 Austin, TX 78753-1024 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of January, 20 25.

APPLICANT/PRINCIPAL

Nuclein, LLC

Authorized Representative

Jeffrey Stukuls, CFO

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Jeff Husk, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

LP 4229 NV (5/21)

Posted February 20, 2020

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Jeff Husk

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and April 27, 2024 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015 and amended on April 27, 2024.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 30th day of January , 2025 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 30th day of January , 2025 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 30th day of January , 2025 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

Secretary

POA 0018 (6/24)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Nuclein, LLC MDEG License # (if applicable) _____

Physical Address 500 Center Ridge Dr, Ste 400

City Austin State TX Zip 78753

Mailing Address (if different from physical address) 8305 Cross Park Dr

City Austin State TX Zip 78754

Telephone 512-354-7242 Website https://nuclein.com

Licensing Company Email jeffrey@nuclein.com

Section 2: Personal Information

First Jeffrey Middle Alan Last Stukuls

Alias(es, nicknames, name changes, etc.) Jeffery

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Austin State TX Zip [redacted]

Telephone [redacted] Email jeffrey@nuclein.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MIT Extension School & Entrepreneur's Organization		06/10-05/12	
Address	**City**	**State**	**Zip**
500 Montgomery Street, Suite 600	Alexandria	VA	22314
Diploma/Degree obtained, if any			
Entrepreneurial Master's Program Graduate			

School Name		From - To (MM/YY – MM/YY)	
Bentley University		09/88 - 05/96	
Address	**City**	**State**	**Zip**
175 Forest Street	Waltam	MA	02452
Diploma/Degree obtained, if any			
Bachelor of Science Accountancy, Minor in Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Boca Raton Community High School		08/84 - 05/88	
Address	**City**	**State**	**Zip**
1501 NW 15th Ct	Boca Raton	FL	33486
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/06 - current	[redacted]	Austin	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Nuclein, LLC		05/20 - current	
Business Address	**City**	**State**	**Zip**
500 Center Ridge Dr, Ste 400	Austin	TX	78753
Phone	**Title**	**Number of Employed Hours**	
512-354-7242	CFO	11,000	

Description of Duties

Providing strategic, financial, and operational leadership as well capital and risk management at a medical device company that offers a cutting-edge, FDA 510(k) cleared and CLIA waived, point-of-care molecular diagnostic system.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/31/2025
Date

I, Jeffrey Stukuls, **certify that as the MDEG Administrator for**

Nuclein, LLC,

that I (initial that you have read and meet the following requirements):

1. JS Have a high school diploma or its equivalent;
2. JS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Stukuls
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/31/2025
Date

Board Use Only	Date Received: 2/10/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nuclein, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 500 Center Ridge Dr, Ste 400

City: Austin State: TX Zip: 78753

Mailing Address (if different from physical address): 8305 Cross Park Dr

City: Austin State: TX Zip: 78754

Telephone: 512-354-7242 Website: https://nuclein.com

Licensing Company Email: jeffrey@nuclein.com

Section 2: Personal Information

First: Steven Middle: Last: Back

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Austin State: TX Zip: [redacted]

Telephone: [redacted] Email: steve@nuclein.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Dallas		08/96 - 05/98	
Address	**City**	**State**	**Zip**
1845 East Northgate Drive	Irving	TX	75062
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Texas at Arlington		08/85 - 05/89	
Address	**City**	**State**	**Zip**
701 S Nedderman Dr	Arlington	TX	76019
Diploma/Degree obtained, if any			
Master of Science in Electrical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Wright State University		09/80 -06/84	
Address	**City**	**State**	**Zip**
3640 Colonial Glenn Hwy	Dayton	OH	45435
Diploma/Degree obtained, if any			
Bachelor of Science in Systems Engineering - Electrical			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/08 - current	[redacted]	Austin	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Nuclein, LLC			08/22 - current	
Business Address		**City**	**State**	**Zip**
500 Center Ridge Dr, Ste 400		Austin	TX	78753
Phone	**Title**		**Number of Employed Hours**	
512-720-5011	COO		6,000	
Description of Duties				
Leading all manufacturing and supply chain operations for PCR-based in-vitro diagnostics (IVD) medical devices, including software, hardware, controls, reagents, and cartridges (tests).				

Business Name			From - To (MM/YY – MM/YY)	
Luminex Corporation (now Diasorin)			06/08 - 12/21	
Business Address		**City**	**State**	**Zip**
12212 Technology Blvd #130		Austin	TX	78727
Phone	**Title**		**Number of Employed Hours**	
512-290-8020	VP of Quality Assurance and Regulatory Affairs		32,000	
Description of Duties				
Led the Quality and Regulatory Organizations (staff of 75) for a Molecular Diagnostics medical device manufacturer across 5 North American locations. Prior to that role led manufacturing (staff of 115) cGMP compliant organization.				

Business Name			From - To (MM/YY – MM/YY)	
Abbott Laboratories			06/91 - 05/08	
Business Address		**City**	**State**	**Zip**
1921 Hurd Dr		Irving	TX	75038
Phone	**Title**		**Number of Employed Hours**	
972-518-6000	Sr. Quality Manager		40,000	
Description of Duties				
Implemented and ran Division wide Global Field Quality failure analysis organization. Before that led On-Market engineering support team for all of Abbott's on-market instrument platforms.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Steven Back, **certify that as the designated representative for**

Nuclein, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SB I am at least 21 years of age;
3. SB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Steven Back

Print Name (First, Last)

Steven Back

Original Signature (electronic, copies or stamps not accepted)

4 Feb 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Back

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~2/3/2025~~ 4 Feb 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Steven Back, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4 Feb 2025

Date

Subscribed and Sworn to before me this 4 day of February, 2025

Notary Public Signature

JEANNIE PHIPPS
ID #129653533
My Commission Expires
December 17, 2025

JEANNIE PHIPPS
ID #129653533
My Commission Expires
December 17, 2025
[Seal]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Nuclein, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 500 Center Ridge Dr, Ste 400

City: Austin State: TX Zip: 78753

Mailing Address (if different from physical address): 8305 Cross Park Dr

City: Austin State: TX Zip: 78754

Telephone: 512-354-7242 Website: https://nuclein.com

Licensing Company Email: jeffrey@nuclein.com

Section 2: Personal Information

First: Alan Middle: Robert Last: Blake

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addr[redacted]

City: Austin State: TX Zip: [redacted]

Telephone: [redacted] Email: alan@nuclein.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Yorktown High School		9/91 - 6/95	
Address	**City**	**State**	**Zip**
2727 Crompond Road	Yorktown	NY	10598
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Binghamton University			
Address	**City**	**State**	**Zip**
4400 Vestal Pkwy E	Binghamton	NY	13902
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
The University of Texas at Arlington		8/96 - 5/97	
Address	**City**	**State**	**Zip**
701 S Nedderman Dr	Arlington	TX	76019
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
The University of Texas at Austin		8/97 - 8/01	
Address	**City**	**State**	**Zip**
2515 Speedway	Austin	TX	78712
Diploma/Degree obtained, if any			
Bachelor in Business Administration			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/11 - present	[redacted]	Austin	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Nuclein, LLC			5/17 - present	
Business Address		**City**	**State**	**Zip**
8305 Cross Park Drive		Austin	TX	78754
Phone	**Title**			
(888) 992-3274	Chief Executive Officer / Board Member			

Description of Duties

As the CEO, I am responsible for executive leadership of the company. I am also a Board Member.

Business Name			From - To (MM/YY – MM/YY)	
Yorktown Technologies, LP			11/01 - 8/19	
Business Address		**City**	**State**	**Zip**
8911 N. Capital of Texas Hwy, Suite 3150		Austin	TX	78759
Phone	**Title**			
(512) 940-3159	Chief Executive Officer			

Description of Duties

As the CEO, I was responsible for executive leadership of the company. I also served on the board of GloFish, LLC, which was the General Partner of Yorktown Technologies, LP.

Business Name			From - To (MM/YY – MM/YY)	
GloFish, LLC			11/01 - 8/19	
Business Address		**City**	**State**	**Zip**
8911 N. Capital of Texas Hwy, Suite 3150		Austin	TX	78759
Phone	**Title**			
(512) 940-3159	Chief Executive Officer / Board Member			

Description of Duties

As the CEO, I was responsible for executive leadership of the company, which was the General Partner of Yorktown Technologies, LP. I also served on the Board as a Board Member.

Business Name			From - To (MM/YY – MM/YY)	
Falcon Structures			12/18 - 12/23	
Business Address		**City**	**State**	**Zip**
7717 Gilbert Rd, Manor		Manor	TX	78653
Phone	**Title**			
(512) 231-1010	Board Member			

Description of Duties

I served on the Board as a Board Member.

Business Name			From - To (MM/YY – MM/YY)	
PrideBites, LLC			10/14 - 9/17	
Business Address		**City**	**State**	**Zip**
3616 Far W Blvd Suite #117-356		Austin	TX	78731
Phone	**Title**			
(424) 256-0102	Board Member			

Description of Duties

I served on the Board as a Board Member.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alan Blake

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 4, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Alan Blake, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

February 4, 2025

Date

Subscribed and Sworn to before me this 4 day of February 2025

Jeannie Phipps

Notary Public Signature

JEANNIE PHIPPS
ID #129653533
My Commission Expires
December 17, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Nuclein, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 500 Center Ridge Dr. Ste 400

City: Austin State: TX Zip: 78753

Mailing Address (if different from physical address): 8305 Cross Park Dr

City: Austin State: TX Zip: 78754

Telephone: 512-354-7242 Website: https://nuclein.com

Licensing Company Email: jeffrey@nuclein.com

Section 2: Personal Information

First: Richard Middle: James Last: Crockett

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Austin State: TX Zip: [redacted]

Telephone: [redacted] Email: rich@nuclein.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Yorktown High School			09/91 - 05/95	
Address		City	State	Zip
2727 Crompond Road		Yorktown Heights	NY	10598
Diploma/Degree obtained, if any				
Regents High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Yale University				
Address		City	State	Zip
2 Whitney Avenue		New Haven	CT	06520
Diploma/Degree obtained, if any				
Intensive Bachelor of Science (B.S.) in Molecular, Cellular, and Developmental Biology				
School Name			From - To (MM/YY – MM/YY)	
Yale University School of Medicine				
Address		City	State	Zip
333 Cedar Street		New Haven	CT	06510
Diploma/Degree obtained, if any				
Doctor of Medicine (M.D.)				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/17 - Present	[redacted]	Austin	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
07/15 - 07/17		Austin	TX	
From - To (MM/YY – MM/YY)		City	State	
02/10 - 07/15		Wilton	CT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Nuclein, LLC			06/17 - 04/24	
Business Address	**City**		**State**	**Zip**
8305 Cross Park Drive	Austin		TX	78754
Phone	**Title**			
512-774-6612	President			
Description of Duties				
Product development, R&D, Intellectual Property, Regulatory, Management				

Business Name			From - To (MM/YY – MM/YY)	
Yorktown Technologies, LP			11/01 - 06/17	
Business Address	**City**		**State**	**Zip**
8911 N Capital of Texas Hwy, Suite 3150	Austin		TX	78759
Phone	**Title**			
512-900-4466	President			
Description of Duties				
Product development, R&D, Intellectual Property, Regulatory, Management				

Business Name			From - To (MM/YY – MM/YY)	
Crockett Holdings, LLC			10/07 - Present	
Business Address	**City**		**State**	**Zip**
7301 N FM 620 Rd., Suite 155-119	Austin		TX	78726
Phone	**Title**			
203-687-7019	President			
Description of Duties				
Business Consulting				

Business Name			From - To (MM/YY – MM/YY)	
Maruku Investments, LLC			05/17 - Present	
Business Address	**City**		**State**	**Zip**
7301 N FM 620 Rd., Suite 155-119	Austin		TX	78726
Phone	**Title**			
203-687-7019	President			
Description of Duties				
Passive Investing				

Business Name			From - To (MM/YY – MM/YY)	
GloFish, LLC			11/01 - 05/17	
Business Address	**City**		**State**	**Zip**
8911 N Capital of Texas Hwy, Suite 3150	Austin		TX	78759
Phone	**Title**			
512-940-3159	President			
Description of Duties				
Product development, R&D, Intellectual Property, Regulatory, Management				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard, Crockett

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 3, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, RICHARD CROCKETT, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Feb 4, 2025

Date

Subscribed and Sworn to before me this 4 day of February 2025

Jeannie Phipps

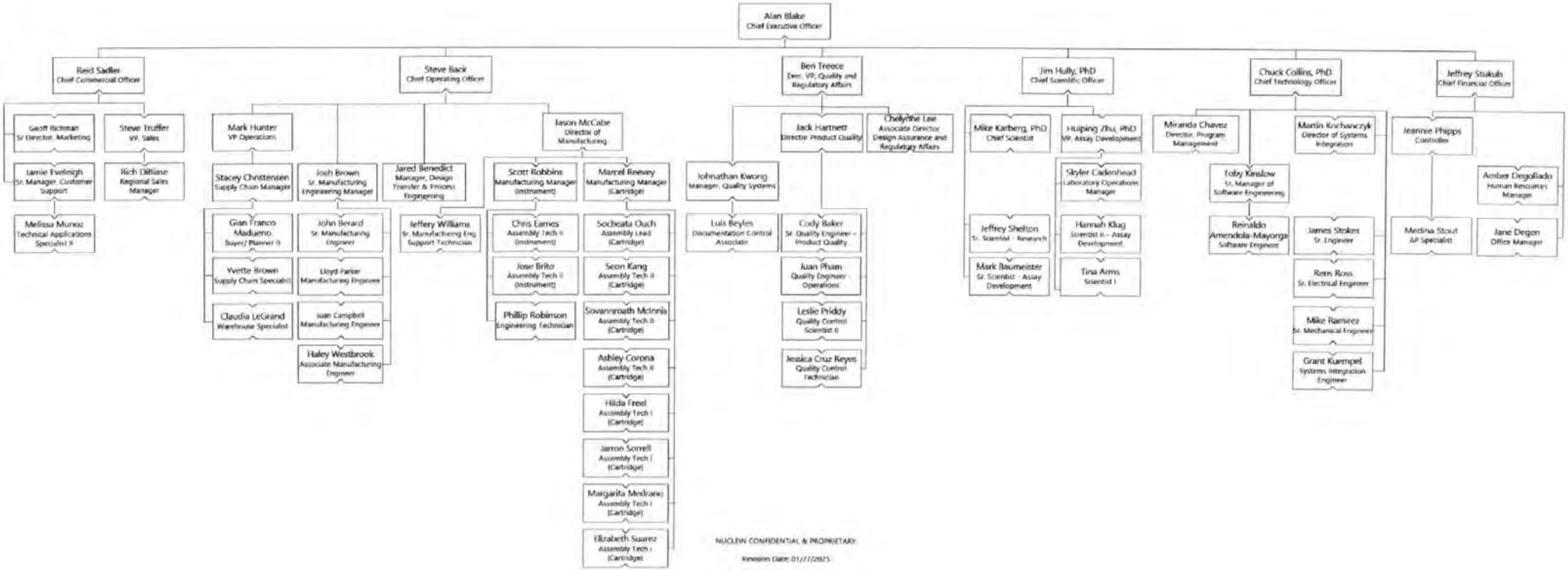
Notary Public Signature

JEANNIE PHIPPS
ID #129653533
My Commission Expires
December 17, 2025

(Seal)

Employees

Nuclein



4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03552	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Kuehne + Nagel Inc.

Physical Address: 2600 Regent Blvd

City: Dallas State: TX Zip: 75261

Mailing Address (if different from physical address): 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 201-413-5500 Website: https://us.kuehne-nagel.com/

Name of Designated Representative (DR): Jenna Bustos

Licensing Company Email: qshepharma.us@kuehne-nagel.com DR Email: jenna.bustos@kuehne-nagel.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3rd Party Logistics Provider

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 11/18/2024

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: FFF Enterprises, Inc
Address: 1650 Lakeside Pkwy, #404 City: Flower Mound State: TX Zip: 75028

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): Kuehne + Nagel Holdings Inc.
Corporation/Organization Name: Kuehne + Nagel Inc.
Mailing Address: 10 Exchange Place 20th Floor
City: Jersey City State: NJ Zip: 07302
Telephone: 201-413-5500 Email: qshepharma.us@kuehne-nagel.com
Contact Person Name: Natalie Martino

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kuehne + Nagel Inc.

Facility Name

Dan Osterberg

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/18/2024

Date

Board Use Only	Date Received: 12/5/24	Amount: $1000 CK 13445

KUEHNE+NAGEL

Owner:
Kuehne + Nagel Investment, LLC
10 Exchange Place 19th floor, Jersey City NJ 07302
FEIN: 22-3176791
100% Ownership

List of Officers:

Marcus Bennett, President/CEO

[redacted]

Dan Osterberg, CFO

[redacted]

Richard J Kaluzinski, Secretary, National Legal Counsel

[redacted]

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	KUEHNE + NAGEL INC.
DOS ID Number:	200052
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/30/1966
Effective Date:	05/01/2023
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 16, 2024 at 04:29 P.M.

WALTER T. MOSLEY
Secretary of State

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006589450 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

KUEHNE + NAGEL INC CORP HO
10 EXCHANGE PL 20TH FLR
JERSEY CITY NJ 07302

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

KUEHNE + NAGEL INC

2600 REGENT BLVD DFW AIRPORT
DALLAS, TX 75261

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003718
Expires: May 15, 2025

NON-TRANSFERABLE

Commissioner

517433

License Number: 1003718 ***Current Date: 03/19/2025 10:28 AM***

Name:	**KUEHNE + NAGEL INC**
License Type:	**Prescription Drug Distributor**
License Status:	**Current**
Expiry Date:	**05/15/2025**
Effective Rank Date:	**10/03/2023**
Modifier(s):	**Other Operation**
	Prescription
	Non Prescript

Addresses

Mailing Address	Address	KUEHNE + NAGEL INC CORP HQ JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302
Physical Loc	Address	KUEHNE + NAGEL INC 2600 REGENT BLVD DFW AIRPORT DALLAS , TX DALLAS 75261 US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
KUEHNE + NAGEL INC	**Owner #A036489** **Status:** **Current** **Expiration Date:**	JERSEY CITY , NJ OUT OF STATE/UNKNOWN 07302 US

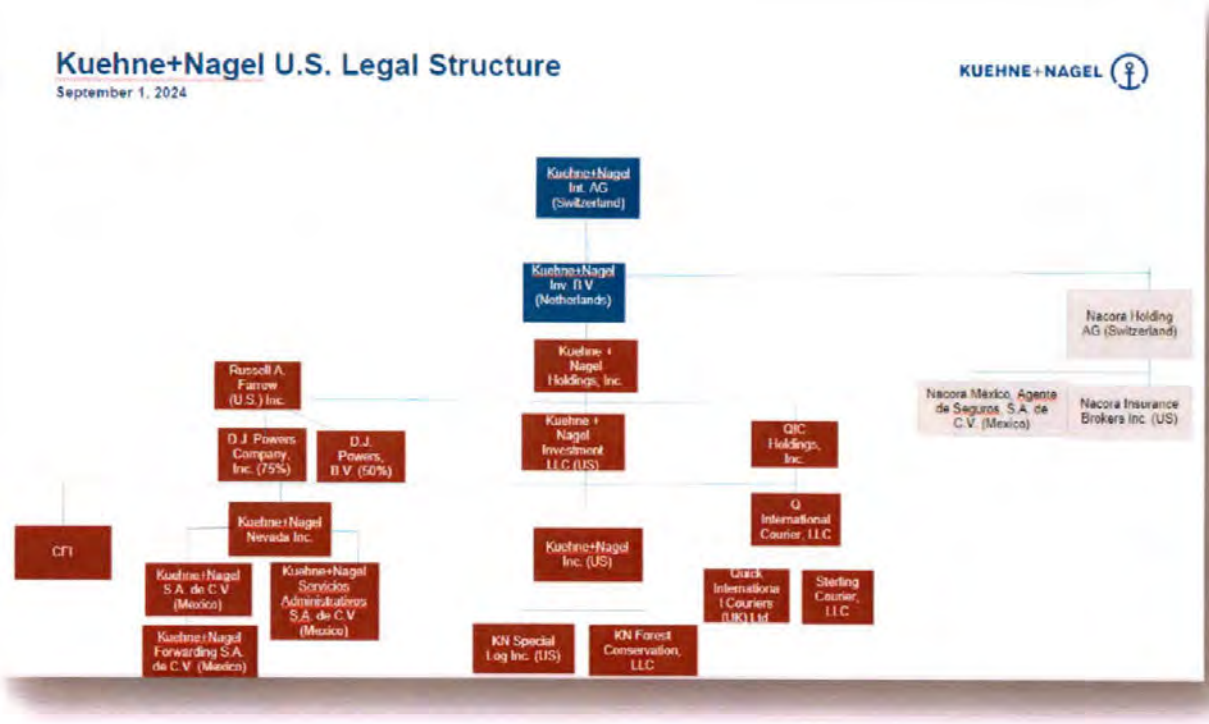
List of License-DFW

Type	Company	Facility	Jurisdiction	Requirement	Number	Status	Issue Date	Expiration
State Licen	Kuehne + N	Dallas, TX	US-AK	Third-Party Logistics Provider	212212	Active	7/18/2023	6/30/2026
State Licen	Kuehne + N	Dallas, TX	US-AR	Wholesale Distributor	WD05877	Active	7/19/2023	12/31/2024
State Licen	Kuehne + N	Dallas, TX	US-AZ	Third Party Logistics Provider	L000450	Active	12/21/2023	10/31/2025
State Licen	Kuehne + N	Dallas, TX	US-CA	Third Party Logistics Provider	NPL 1413	Active	5/1/2024	5/1/2025
State Licen	Kuehne + N	Dallas, TX	US-CT	Wholesaler of Drugs, Cosmetics, & Medical Devices	CSW.0005325	Active	7/1/2024	6/30/2025
State Licen	Kuehne + N	Dallas, TX	US-DC	Device Distributor	DCDED0035	Active		9/30/2025
State Licen	Kuehne + N	Dallas, TX	US-IA	Medical Device Distribution	41773	Active	8/16/2023	12/31/2024
State Licen	Kuehne + N	Dallas, TX	US-KS	Third Party Logistics Provider	23-121089	Active	7/28/2023	6/30/2025
State Licen	Kuehne + N	Dallas, TX	US-KY	Third Party Logistics Provider	TPL00451	Active	8/18/2023	6/30/2025
State Licen	Kuehne + N	Dallas, TX	US-LA	Third Party Logistics Provider	10983	Active	7/10/2023	12/30/2024
State Licen	Kuehne + N	Dallas, TX	US-MI	Wholesale Drug Distributor	5306007565	Active	10/16/2023	10/16/2025
State Licen	Kuehne + N	Dallas, TX	US-MS	Third Party Logistics Provider	18747	Active	8/29/2023	12/31/2024
State Licen	Kuehne + N	Dallas, TX	US-MT	Wholesale Drug Distributor	PHA-WDD-LIC-98182	Active	8/7/2023	11/30/2024
State Licen	Kuehne + N	Dallas, TX	US-NH	Manufacturer / Distributor / Wholesaler / Broker	7835	Active	7/19/2023	7/31/2025
State Licen	Kuehne + N	Dallas, TX	US-NV	Wholesaler	WH03552	Active		10/31/2026
State Licen	Kuehne + N	Dallas, TX	US-OR	Drug Distribution Agent	DDA-0000664	Active	8/17/2023	9/30/2025
State Licen	Kuehne + N	Dallas, TX	US-PA	Devices-Medical: Manufacturer, Distributor or Retailer	6000010589	Active	3/31/2023	4/30/2025
State Licen	Kuehne + N	Dallas, TX	US-SC	Non-Resident Third Party Logistics Provider	21676	Active	11/30/2023	6/30/2025
State Licen	Kuehne + N	Dallas, TX	US-TN	Third Party Logistics Provider	9420	Active	8/21/2023	8/31/2025
State Licen	Kuehne + N	Dallas, TX	US-TX	Multiple Products with Non-Prescription Drugs	1002056	Active	5/30/2023	4/19/2025
State Licen	Kuehne + N	Dallas, TX	US-TX	Prescription Drug Distributor	1003718	Active	10/3/2023	5/15/2025
State Licen	Kuehne + N	Dallas, TX	US-TX	Warehouse Operator	1001539	Active	3/28/2023	3/8/2025
State Licen	Kuehne + N	Dallas, TX	US-UT	Pharmacy - Class E	13516577-1714	Active	7/28/2023	9/30/2025
State Licen	Kuehne + N	Dallas, TX	US-VA	Non-Resident Third Party Logistics Provider	242000273	Active	11/1/2023	2/28/2025

KUEHNE+NAGEL

Kuehne+Nagel U.S. Legal Structure

September 1, 2024



Anticipated Kuehne+Nagel U.S. Legal Structure

December 1, 2024

KUEHNE+NAGEL

Kuehne + Nagel Inc.

10 Exchange Pl
Floor 20
Jersey City, NJ 07302

Tel.: +1 484.995.6137
ria.philip@kuehne-nagel.com

us.kuehne-nagel.com
www.kuehne-nagel.com

AGREEMENT
AND
PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER, dated as of November 11, 2024 (this "Plan of Merger"), is between Kuehne + Nagel Investment LLC, a New Jersey Limited Liability Company ("Merged LLC"), and Kuehne + Nagel Holdings, Inc., a Delaware corporation ("Surviving Corporation").

W I T N E S S E T H:

WHEREAS, Merged LLC has a single member to wit, the Surviving Corporation; and

WHEREAS, Surviving Corporation is authorized to issue a total of 100 shares of capital stock, consisting of 200 shares of common stock, par value $0.01 per share ("Surviving Corporation Common Stock"), of which, as of the date hereof, 100 shares of Common Stock are issued and outstanding; and

WHEREAS, the sole member and the Managers of the Merged LLC and the Board of Directors of the Surviving Corporation, respectively, approve and deem it advisable that Merged LLC and Surviving Corporation, respectively, consummate the Merger (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements contained in this Plan of Merger, the parties to this Plan of Merger hereby agree that Merged LLC shall be merged (the "Merger") with and into Surviving Corporation in accordance with applicable laws and upon the terms and subject to the conditions set forth as follows:

1. The Merger. At such time agreed between Merged LLC and Surviving Corporation, a certificate of merger evidencing the Merger shall be filed with each of the Office of the Secretary of State of the State of New Jersey pursuant to the Title 42 of the New Jersey Revised Statutes and of the State of Delaware General Corporation Law. The Certificates of Merger shall specify that the Merger shall become effective on December 1, 2024 ("Effective Time"). At the Effective Time, Merged LLC shall be merged with and into Surviving Corporation, and Surviving Corporation shall continue as the surviving corporation. The Surviving Corporation's name shall remain Kuehne + Nagel Holdings, Inc.

2. Certificate of Incorporation and By-laws. The Certificate of Incorporation and By-laws of Surviving Corporation in effect immediately prior to the Effective Time shall be and remain the Certificate of Incorporation and By-laws, respectively, of Surviving Corporation, as the surviving corporation, after the Effective Time, until amended as provided by law.

3. Officers and Directors. From and after the Effective Time, and until they shall have resigned or shall have been legally removed or until their respective successors shall have been elected or appointed and qualified, those persons who are the officers and directors of Surviving Corporation immediately prior to the Effective Time shall be the officers and directors of Surviving Corporation.

4. Effect of the Merger.

4.1 All assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC in and to every type of property (real, personal and mixed) and choses in action, as they exist as of the Effective Time, shall pass and be transferred to and vest in Surviving Corporation, as the surviving corporation, by virtue of the Merger at the Effective Time without any deed, conveyance or other transfer, and all such interests of Surviving Corporation as they exist as of the Effective Time shall remain with Surviving Corporation upon consummation of the Merger. The corporate existence of Surviving Corporation shall continue unaffected and unimpaired upon consummation of the Merger and the separate corporate existence of Merged LLC shall cease at and as of the Effective Time.

4.2 From and after the Effective Time, Surviving Corporation, as the surviving corporation, shall be responsible and liable for all of the liabilities and obligations of Surviving Corporation and Merged LLC existing as of the Effective Time. Any claim existing or action or proceeding pending by or against Surviving Corporation or Merged LLC at the Effective Time may, thereafter, be prosecuted by or against Surviving Corporation, as the surviving corporation, as if the Merger had not taken place or, in connection with any such action or proceeding to which Merged LLC is a party, Surviving Corporation, as the surviving corporation, may be substituted in place of Merged LLC. Neither the rights of creditors nor any liens upon the property of either Surviving Corporation or Merged LLC shall be impaired by reason of the Merger.

5. Effect of Merger on Outstanding Shares.

5.1 *Exchange Ratio*. At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof, all of the issued and outstanding member shares of the Merged LLC shall be cancelled.

5.2 *Closing of Transfer Books*. At the Effective Time, the membership transfer books of Merged LLC shall be closed and no transfer of shares of Merged LLC membership shall thereafter be made. If, after the Effective Time, certificates representing member shares of Merged LLC are presented to the Surviving Corporation, they shall be canceled in accordance with the terms hereof. At and after the Effective Time, the holders of member shares of Merged LLC Stock shall cease to have any rights as members of Merged LLC.

6. Further Assurances. From time to time after the Effective Time, as and when requested by Surviving Corporation, and to the extent permitted by law, the former managers of Merged LLC and the officers and directors of Surviving Corporation shall execute and deliver such assignments, deeds and other instruments and shall take or cause to be taken such further or other action as shall be necessary in order to consummate the Merger, vest or perfect in or to confirm of record or otherwise to Surviving Corporation, as the surviving corporation, title to, and possession of, all of the assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC and Surviving Corporation in and to every type of property (real, personal and

mixed) and choses in action, and otherwise to carry out the purposes of this Plan of Merger, and the proper officers and directors of Surviving Corporation, as the surviving corporation, are fully authorized to take any and all such action in the name of Merged LLC or Surviving Corporation or otherwise.

7. Termination and Amendment. Prior to the Effective Time, this Plan of Merger may be terminated or amended by the mutual consent of the Managers of Merged LLC and the Board of Directors of Surviving Corporation.

8. Counterparts. This Plan of Merger may be signed in any number of counterparts, each of which shall be deemed an original, and all of which shall be deemed but one and the same instrument.

9. Governing Law. This Plan of Merger shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New Jersey or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New Jersey.

IN WITNESS WHEREOF, the parties have duly executed this Plan of Merger as of the date first written above.

KUEHNE + NAGEL INVESTMENT LLC
(Merged LLC)

By: _____
Marcus Bennett, Manager

By: _____
Dan Osterberg, Manager

By: _____
Nadine Jones, Manager

KUEHNE + NAGEL HOLDINGS, INC.
(Surviving Corporation)

By: _____
Name: Dan Osterberg
Title: CFO, Treasurer

Lexon Insurance Company

November 20, 2024

Nevada Board of Pharmacy

Bond Name: KUEHNE + NAGEL INC.
Bond Number: 413722
Amount: $100,000.00
Effective Date: 10/31/2006

Rider Executed and Effective November 20, 2024

The above referenced bond includes the following K+N facility location to ensure sufficient coverage:

1025 Columbia Rd, Suite 110, Plainfield, IN 46168

4080 Executive Drive, Suite 100, Southaven, MS 38672

2555 USA Parkway, Suite 104, McCarran, NV 89434

324 Half Acre Road, Cranbury, NJ 08512

2532 Whilden Drive, Durham, NC 27713

6005 Freeport Avenue, Suite 103, Memphis, TN 38141

2600 Regent Blvd Dallas, TX 75261

1800 Waters Ridge Drive, Suite 100, Lewisville, TX 75057

Nothing herein contained shall be held to vary, alter or waive or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond or policy, other than as above stated.

Lexon Insurance Company

James Reiss, Attorney in Fact

By:

NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0413722

Application/License No. WH00941

Kuehne + Nagel Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is 6005 Freeport Ave #J-122, Memphis TN 38141, as
Address of Applicant/Principal
PRINCIPAL, and International Fidelity Insurance Co., a
Surety Company
corporation organized under the laws of the state of New Jersey
State of Incorporation
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is One Newark Center, Newark NJ 07102 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on _____.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL	SURETY COMPANY
_____ Authorized Representative	International Fidelity Ins. Co. Surety Company's Representative
	Kevin A. Tattam, Attorney-in-fact print name
SIGNED and SEALED in the presence of:	SIGNED and SEALED in the presence of:
_____ Witness	Benny Munoz Witness
_____ Witness	Martino Sessa Witness

Countersigned by:

Margo Ann Smith
Nevada Resident Agent

NEVADA BONDING AGENCY, INC.
P.O. BOX 80987
LAS VEGAS, NV 89180
PHONE (702) 631-0878
FAX (702) 647-5391

POWER OF ATTORNEY

LX - 015431

Lexon Insurance Company

KNOW ALL MEN BY THESE PRESENTS, that **LEXON INSURANCE COMPANY**, a Texas Corporation, with its principal office in Louisville, Kentucky, does hereby constitute and appoint: Kevin Tattam **********

****

its true and lawful Attorney(s)-In-Fact to make, execute, seal and deliver for, and on its behalf as surety, any and all bonds, undertakings or other writings obligatory in nature of a bond.

This authority is made under and by the authority of a resolution which was passed by the Board of Directors of **LEXON INSURANCE COMPANY** on the 1st day of July, 2003 as follows:

Resolved, that the President of the Company is hereby authorized to appoint and empower any representative of the Company or other person or persons as Attorney-In-Fact to execute on behalf of the Company any bonds, undertakings, policies, contracts of indemnity or other writings obligatory in nature of a bond not to exceed $ 7,100,000.00 Seven million one hundred thousand dollars dollars, which the Company might execute through its duly elected officers, and affix the seal of the Company thereto. Any said execution of such documents by an Attorney-In-Fact shall be as binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company. Any Attorney-In-Fact, so appointed, may be removed for good cause and the authority so granted may be revoked as specified in the Power of Attorney.

Resolved, that the signature of the President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Vice President, and the seal of the Company may be affixed by facsimile to any certificate of any such power and any such power or certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certificate so executed and sealed shall, with respect to any bond of undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS THEREOF, **LEXON INSURANCE COMPANY** has caused this instrument to be signed by its President, and its Corporate Seal to be affixed this 2nd day of July, 2003.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

LEXON INSURANCE COMPANY

BY _____
David E. Campbell
President

ACKNOWLEDGEMENT

On this 2nd day of July, 2003, before me, personally came David E. Campbell to me known, who being duly sworn, did depose and say that he is the President of **LEXON INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he executed said instrument on behalf of the corporation by authority of his office under the By-laws of said corporation.

"OFFICIAL SEAL"
MAUREEN K. AYE
Notary Public, State of Illinois
My Commission Expires 09/21/09

_____
Maureen K. Aye
Notary Public

CERTIFICATE

I, the undersigned, Secretary of **LEXON INSURANCE COMPANY**, A Texas Insurance Company, DO HEREBY CERTIFY that the original Power of Attorney of which the foregoing is a true and correct copy, is in full force and effect and has not been revoked and the resolutions as set forth are now in force.

Signed and Sealed at Lombard, Illinois this 31st Day of Oct., 20 08.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

_____
Donald D. Buchanan
Secretary

TEL: (201) 653-6100
BOND FAX: (201) 653-7766
MARINE FAX: (201) 533-8611

EMAIL: bond@intlbondmarine.com
marine@intlbondmarine.com

B&M

INTERNATIONAL BOND & MARINE BROKERAGE, LTD.
Two Hudson Place • 4th Floor • Hoboken, NJ 07030-5515
www.intlbondmarine.com

October 28, 2008

Via Certified Mail / RRR
7005 1820 00006 2888 3457

Attn: Candy
Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, NV 89509 - 3766

Re: Kuehne + Nagel, Inc.
Pharmaceutical Wholesaler Surety Bond
Bond # 413722

Dear Candy:

Enclosed please find the Change in Surety Rider and power of attorney for the above captioned bond. Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company Bond as of the anniversary date of October 31st, 2008. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount remain unchanged.

If you have any questions or require additional information please feel free to contact our office.

Sincerely,

Shayna Betancourt

Shayna Betancourt
Assistant Surety Manage
International Bond & Ma

Enclosure

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:
Attn: Candy
Nevada State board of Pharmacy.
431 W Plumb Lane
Reno, NV 89509

COMPLETE THIS SECTION ON DELIVERY

A. Signature X ☐ Agent ☐ Addressee

B. Received by (Printed Name) L. Hedan C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

NOV 03 2008

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7005 1820 0006 2888 3457

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

Lexon Insurance Company
(a TX Corporation)
256 Jackson Meadows Drive
Hermitage, TN 37076

Bond Rider

Principal: KUEHNE + NAGEL, INC.
Bond Number: 413722
Effective Date of Rider: 10/31/08

Change in Surety

Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company as of the above referenced effective date of the rider. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount, remain unchanged.

Nothing herein contained otherwise shall be held to vary, alter, waive, or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond.

Lexon Insurance Company
Attorney-in-fact, Kevin A. Tattam 143-48-7151

By: _____

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/03/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER

Nacora Insurance Brokers Inc
10 Exchange Place, 20th Floor
Jersey City NJ 07302

CONTACT NAME: Felicia Brown
PHONE (A/C, No, Ext): 201-413-0535 **FAX (A/C, No):** fax number
E-MAIL ADDRESS: felicia.brown@nacora.com

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A :	Zurich American Insurance Company	16535
INSURER B :	American Guarantee & Liability Ins. Co.	26247
INSURER C :		
INSURER D :		
INSURER E :		
INSURER F :		

INSURED

Kuehne + Nagel, Inc.
c/o Nacora Insurance Brokers, Inc.
10 Exchange Place, 20th Floor
Jersey City NJ 07302

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			GLO3373970	1/01/2025	1/01/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X $5,000: BI/PD Deductible						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			AUC379310315	1/01/2025	1/01/2026	EACH OCCURRENCE	$ 20,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 20,000,000
	DED X RETENTION $ 0							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Property (PD & TE)			MCP2906577-26	1/01/2025	1/01/2026	BLANKET LIMIT	$135,805,200

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: 324 Half Acre Road, Cranbury NJ 08512; 2525 Whilden Drive, Durham NC 27713
DFW: 2600 Regent Blvd, Dallas, TX 75261
MEM: 6005 Freeport Ave, Suite 103, Memphis, TN 38141
LJV: 1800 Waters Ridge Dr, Suite 100, Lewisville, TX 75057
SVQ: 4080 Executive Drive, Suite 100, Southaven, MS 38672
PAF: 1025 Columbia Road, Suite 110, Plainfield, IN, 46168
RNO: 2555 USA Parkway, #104, McCarran, NV 89434
Property Coverage includes Business Personal Property and Loss of Business Income & Extra Expense per schedule on file.

CERTIFICATE HOLDER

Wyoming Board of Pharmacy
1712 Carey Avenue, Suite 200
Cheyenne, WY 82002

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Kuehne + Nagel Inc. MDEG License # (if applicable): WH03552

Physical Address: 2600 Regent Blvd

City: Dallas State: TX Zip: 75261

Mailing Address (if different from physical address): 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 201-413-5500 Website: https://us.kuehne-nagel.com/

Licensing Company Email: qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First: Jenna Middle: Rae Last: Bustos

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres[redacted]

City: Carrollton State: TX Zip[redacted]

Telephon[redacted] Email: jenna.bustos@kuehne-nagel.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Waubonsee Community College		2005-2009	
Address	City	State	Zip
4S783 IL-47	Sugargrove	IL	60554
Diploma/Degree obtained, if any			
Associates of Science			

School Name		From - To (MM/YY – MM/YY)	
Waubonsie Valley High School		8/2003-5/2004	
Address	City	State	Zip
2590 Ogden Ave	Aurora	IL	60504
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Sandalwood High School		08/2002-6/2003	
Address	City	State	Zip
2750 John Promenade Blvd.	Jacksonville	FL	32246
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21 to present	[redacted]	Carrollton	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/20-03/21		Montgomery	IL	
From - To (MM/YY – MM/YY)		City	State	
05/18-06/20		Aurora	IL	
From - To (MM/YY – MM/YY)		City	State	
01/16-05/18		Oswego	IL	
From - To (MM/YY – MM/YY)		City	State	
11/14-01/16		Montgomery	IL	
From - To (MM/YY – MM/YY)		City	State	
02/08-11/14		Aurora	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Kuehne + Nagel Inc.			11/2017-present	
Business Address		**City**	**State**	**Zip**
2600 Regent Blvd		Dallas	TX	75261
Phone	**Title**		**Number of Employed Hours**	
630-965-3804	Operations Manager		>6000	

Description of Duties
Responsible for overseeing the day to day operations ensuring a smooth workflow while maintaining high standards of customer service.
Conduct audits to ensure compliance with regulatory requirements is followed for both receiving and shipping of medical devices.
Successfully manage product recalls and adverse event reporting.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Jenna Bustos
Original Signature (electronic, copies or stamps not accepted)

02/03/2025
Date

I, Jenna Bustos, **certify that as the MDEG Administrator for**

Kuehne + Nagel Inc.,

that I (initial that you have read and meet the following requirements):

1. JRB Have a high school diploma or its equivalent;
2. JRB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JRB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JRB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jenna Bustos
Print Name (First, Last)

Jenna Bustos
Original Signature (electronic, copies or stamps not accepted)

02/03/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kuehne + Nagel Inc.

Pharmacy/Wholesaler License # (if applicable) WH03552

Physical Address 2600 Regent Blvd

City Dallas State TX Zip 75261

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Jenna Middle Rae Last Bustos

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Carrollton State T X Zip [redacted]

Telephone [redacted] Email jenna.bustos@kuehne-nagel.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Waubonsee Community College		2005-2009	
Address	**City**	**State**	**Zip**
4S783 IL-47	Sugar Grove	IL	60554
Diploma/Degree obtained, if any			
Associates of Science			

School Name		From - To (MM/YY – MM/YY)	
Waubonsie Valley High School		08/2003-05/2004	
Address	**City**	**State**	**Zip**
2590 Ogden Ave	Aurora	IL	60504
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Sandalwood High School		08/2002-06/2003	
Address	**City**	**State**	**Zip**
2750 John Promenade Blvd.	Jacksonville	FL	32246
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21 to present	[redacted]	Carrollton	TX	[redacted]
06/20-03/21		Montgomery	IL	
05/18-06/20		Aurora	IL	
01/16-05/18		Oswego	IL	
11/14-01/16		Montgomery	IL	
02/08-11/14		Aurora	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Kuehne + Nagel Inc.			11/2017-Present	
Business Address		City	State	Zip
2600 Regent Blvd		Dallas	TX	75261
Phone	Title		Number of Employed Hours	
630-965-3804	Operations Manager		>6000	
Description of Duties				
Responsible for overseeing the day to day operations ensuring a smooth workflow while maintaining high standards of customer service. Conduct audits to ensure compliance with regulatory requirements is followed for both receiving and shipping of medical devices. Successfully manage product recalls and adverse event reporting.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 11/11/24

I, Jenna Bustos, **certify that as the designated representative for**

Kuehne + Nagel Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JRB I am at least 21 years of age;
3. JRB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JRB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JRB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JRB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JRB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jenna Bustos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 11/11/2024

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jenna Bustos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, Jenna Bustos, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Date 11/13/2024

Subscribed and Sworn to before me this 13 day of November 2024

Nola K Burton

Notary Public Signature

NOLA K BURTON
Notary ID #133191990
My Commission Expires
July 6, 2025

(Seal)

DALLAS
EMPLOYEE NAMES:
Angel Martinez
Denver Bell
Gabriela Martinez
Erina Castillo
Ricardo Robles
Iderkee Pacheco
George Threadgill
Siole Barboza
Ines Camacho
Ana Carvajal
Stephen Cowden
Jessica Sutherland
Donta Aaron
Tanisha McCoy
Jermi McCoy
Aniorfi Vasquez
Peter Mang
Temi Akingboye
Shane Robinson
Indira Jardines
Brian Anderson
Jeffery Shemayme
Manuel Rangel
Stefhania Vargas
Gabriela Lopez
Danny Wesley
Eugenia Figueroa
Ismael Canhonga
Torrance Brown
Valerie Contreras
Daniela Lopez
Octavia Kamara
Kamila Molina
Arthura Murray
Peyton Nokes
Dondre Cummings
Pavel Chiryatev
Jimena Garcia
Oswayrie Burgos
Julio Ospino

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
Consumer Protection Division
PO Box 149347, Austin, TX 78714
(512) 834-6660

Name	KUEHNE + NAGEL INC KUEHNE + NAGEL INC	License Type	Multiple Products
Address	2600 REGENT BLVD DALLAS TX 75261	License Number	1002056
Inspection Type	Periodic/Routine	Inspection Number	250527
Inspector	VILLA, MIGUEL URIEL	Inspection Date	06/29/2023

NOTICE OF INSPECTIONAL OBSERVATIONS

This notice is to acknowledge that the Texas Department of State Health Services (DSHS) conducted an inspection of your business on the date listed above. The information that has been gathered is subject to further department review and you may receive additional correspondence as a result.

There is no deficiency/violation cited or noted within the scope of this inspection/visit.

Inspector:

VILLA, MIGUEL URIEL

Miguel Villa

Date: 06/29/2023

Firm Representative:

Sharon McCabe

Sharon McCabe

Date: 06/29/2023

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☒ Hospital (# beds 808)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☒ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Renown Regional Medical Center Specialty Care Center Pharmacy

Physical Address: 10201 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-982-4266 Toll Free # (NAC 639.708, NRS 639.23286): NA

Fax: 775-982-5740 Contact Email: adam.porath@renown.org

Website: renown.org

Nevada Business License # (if applicable) NV19851012417

Supervising/Managing Pharmacist Name (NRS 639.220): Maura O'Brien

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19478

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Maura O'Brien	NV Pharmacist Registration #: 19478
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Renown Health

Corporation/Organization Name: Renown Regional Medical Center

Mailing Address: 1155 Mill Street

City: Reno State: NV Zip: 89502

Telephone: 775-982-4100 Email: anna.loomis@renown.org

Contact Person Name: Anna Loomis

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for Renown Regional Medical Center Specia (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Anna Loomis

Print Name of Authorized Person

Anna Loomis

Original signature of Authorized Person (copies or stamps not accepted)

5/18/25

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Maura O'Brien Pharmacist Registration #: 19478

Pharmacy Name: Renown Regiona Medical Center Specialty Care Center Pharmacy

Initial each statement below to indicate you have read and agree with the following:

MO I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

MO I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

MO I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

MO I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

MO I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maura O'Brien
Original signature of Managing Pharmacist (copies or stamps not accepted)

3/18/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANNA LOOMIS

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/18/25

Date

Board Use Only	Date Received: 3/20/25	Amount: $500-CC

Renown Health Board

Cliff Deveny, MD

Bijel Doshi

Brian Erling, MD

Tammy Dermody, Chair

Adam Kramer

Stephanie Lepori

Marc Mora, MD

Jeff Resnik

Brian Sandoval

Renown Regional Medical Center Officers

Chris Nicholas – CEO

Brett Moore – CFO

Amy McCombs – COO

Adam Porath, PharmD – VP of Pharmacy Services

There no owners or stockholders of Renown Regional Medical Center. It is a local, non-for-profit organization.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am; by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

RENOWN REGIONAL MEDICAL CENTER

Organizational Documents on File	Filing Date
Amended and Restated Articles	02/04/2016
Amendment	10/16/2006
Amendment	11/21/1986
Articles of Incorporation	07/29/1985

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence RENOWN REGIONAL MEDICAL CENTER, as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of tbe State of Nevada since 07/29/1985, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/03/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412035232956
You may verify this certificate online at
https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Renown Regional Medical Center Specialty Care Center Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 10201 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775-982- Website: renown.org

Licensing Company Email:

Section 2: Personal Information

First: Maura Middle: Jean Last: O'Brien

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Reno State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota College of Pharmacy		8/2003 - 5/2007	
Address	**City**	**State**	**Zip**
308E Harvard St	Minneapolis	MN	66566
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota-Duluth		8/1999 - 5/2003	
Address	**City**	**State**	**Zip**
1049 University Dr	Duluth	MN	55812
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Faribault Senior High School			
Address	**City**	**State**	**Zip**
330 9th Ave SW	Faribault	MN	55021
Diploma/Degree obtained, if any			
High Schoold Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2000 - present	[redacted]	Reno	NV	[redacted]
3/2017 - 5/2000		Reno	NV	
10/2013 - 7/2017		Bloomington	MN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Renown Regional Medical Center			5/2021 - present	
Business Address		**City**	**State**	**Zip**
1155 Mill Street		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775-982-3637	Pharmacist Supervisor		8,500	
Description of Duties				
Day to day operations management of inpatient pharmacy and outpatient infusion pharmacy.				

Business Name			From - To (MM/YY – MM/YY)	
Raley's			12/2018 - 5/2021	
Business Address		**City**	**State**	**Zip**
1441 Mayberry Dr		Reno	NV	89509
Phone	**Title**		**Number of Employed Hours**	
775-786-3655	Pharmacy Team Leader		7040	
Description of Duties				
Day to day management of retail pharmacy operations				

Business Name			From - To (MM/YY – MM/YY)	
Fairview Pharmacy Services			5/2011 - 8/2016	
Business Address		**City**	**State**	**Zip**
		Bloomington	MN	
Phone	**Title**		**Number of Employed Hours**	
	Pharmacy Manager		12,000	
Description of Duties				
Day to day management of retail pharmacy operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Maura O'Brien, **certify that as the designated representative for**

Renown Regional Medical Center -,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MO I am at least 21 years of age;
3. MO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Maura O'Brien

Print Name (First, Last)

Maura O'Brien

Original Signature (electronic, copies or stamps not accepted)

3/25/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maura O'Brien

Print Name (First, Last)

Maura O'B

Original Signature (electronic, copies or stamps not accepted)

3/26/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Maura O'Brien, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Maura O'B

Original Signature

3/26/25

Date

Subscribed and Sworn to before me this 26th day of March 2025

Suzanne M. Peters

Notary Public Signature

SUZANNE PETERS
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 18-3422-2
MY APPT. EXPIRES JULY 06, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Renown Regional Medical Center Specialty Care Center Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 10201 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-982-4266 Toll Free # (NAC 639.708, NRS 639.23286): NA

Fax: 775-982-5740 Contact Email: _____

Website: renown.org

Nevada Business License # (if applicable) NV19851012417

Supervising/Managing Pharmacist Name (NRS 639.220): Maura O'Brien

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19478

Name of Designated Person(s) as defined by revised USP-797 guidelines: Ryan Lampien

Email of Designated Person(s): ryan.lampien@renown.org

Telephone of Designated Person(s): 775-982-4039

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ☐ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Initial certification scheduled May 7-May 9, 2025.

6. What is the frequency of the recertification for the ISO classified areas? Will be every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☐ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

NIOSH category 1
NIOSH category 2

CIVI Antibiotics

12. What laboratory performs your sterility or endotoxin testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?
Technician will visually inspect product for any deviation from the expected appearance. Pharmacist will then visually inspect the product for deviations from the expected appearance, and container closure integrity.

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months for sterile compounding personnel
Every 12 months for direct oversight personnel

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
On the job training is provided to all personnel who will compound or have direct oversight of compounding personnel. Training and observations will be performed by the designated person or an assigned trainer. Training consists of appropriate hand hygeine, garbing, cleaning and disinfecting, calculations, measuring and mixing, use of equipment, documentation of compounding process, proper use of PECs, materials movement, and aseptic technique. Didactic training is conducted initially, and annually thereafter for sterile compounding personnel and for direct oversight of compounding personnel.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Daily cleaning for PECs, pass-through chambers, work-surfaces and high-touch areas, and floors.
Weekly cleaning for areas beneath the worksurface in C-PECs.
Monthly cleaning for all surfaces within the cleanroom space to include PECs/C-PECs, floors, walls, work surfaces, carts, shelves, bins, pass-through chambers.
Daily CD3 activities for floors and high-touch areas within the C-SEC.

Cleaning agents used at Renown Health include:
- Sterile TB1-3300 wipers for daily, weekly, and monthly cleaning of the PECs/C-PECs.
- Sterile 70% IPA wipers for daily, weekly, and monthly sanitizing of the PECs/C-PECs.
- Sterile PeridoxRTU for the weekly and monthly cleaning of the PECs/C-PECs.
- PREempt Plus for daily cleaning of SECs (i.e., work surfaces, high-touch areas, floors).
- PeridoxRTU for the monthly cleaning of the SEC/C-SEC.
- PeridoxRTU for deactivation and decontamination activities during the CD3 process.

17. Who performs the sterile compounding process at your facility?

Personnel designated as sterile compounding personnel.

18. Who is responsible and accountable for the sterile compounding process at your facility?
Personnel designated as direct oversight personnel, the Designated Person, Pharmacist in Charge, and Director of Pharmacy Operations.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
No shipping/mailing of CSPs will be conducted by Renown Health

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class II Type A2 BSCs		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: Equashield		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

***

Education is provided to the consumer via Renowns Hazardous Communication program, with assigned eLearning done annually.

Education to the patient on proper handling of hazardous drug products is performed by our nursing partners. Spill kits and educational videos are provided. Patients sign a consent to understanding of education provided.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
This follows USP 797/800 competency standards in relation to sterile hazardous compounding.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maura O'Brien

Name of Person who Completed the Form

Pharmacist in Charge

Title

Maura O'Brien

Signature (copies or stamps not accepted)

3/19/25

Date

Board Use Only	Date Received: 3/20/25 Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Inspection: Instruction Sheet and Form

(Revised 12/16/2024)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed Sterile Compounding Inspection form along with prior year inspection form.
2. Most recent certification report for ISO classified areas. Documentation of corrective action taken by facility for any failures documented on the certification report.
3. Prior 12 months of aseptic manipulation competency evaluations. Documentation of corrective action taken by facility for any failures.
4. Prior 12 months of competency documentation for personnel.
5. Prior 12 months of garbing competency for compounding personnel.
6. Prior 12 months of Microbiological air and surface monitoring results.
7. Sterility testing data if applicable.
8. Endotoxin testing data if applicable.
9. Examples of Master Formulation Records.
10. Examples of compounding records.
11. Stability data obtained using a stability-indicating analytical method for Category 3 products.
12. Cleaning logs for ISO classified areas.
13. SOP's relevant to the sterile compounding process.

Compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk substance to create a sterile medication.

Specific Practices:

Allergenic Extracts are described in section 21 of the chapter.

When compounding activities require the manipulation of a patient's blood-derived or biological material, the manipulations must be clearly separated from other compounding activities to avoid any cross-contamination.

Repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements of USP-797.

Compounding of sterile hazardous drugs must additionally comply with USP-800.

Compounding of radiopharmaceuticals is not required to meet the standards of this chapter as they are subject to the requirements of USP-825.

Administration is out of the scope of USP-797.

Compounding of CSPs for direct and immediate administration to a patient is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs when all of the conditions listed in USP-797 are met.

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside an ISO 5 environment.

Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with USP-797.

Beyond Use Dates for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling.

Pharmacy Information	
Date Completed:	3/19/2025
Pharmacy Name:	Renown Regional Medical Center Specialty Care Center Pharmacy
Pharmacy License #:	
Pharmacy Address:	10201 Double R Blvd
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	Maura O'Brien
Managing Pharmacist start date:	
Name of Designated person(s):	Ryan Lampien

List of compounding personnel approved to compound sterile products
(Make copies of this page if additional space is needed)

#	Name (First, Last)	License Number	Position	Category Qualified to Compound
1	Minden Abele	PT21092	Oncology Pharmacy Technici	Category 1 and 2
2	Melissa Aguilar	PT12909	Oncology Pharmacy Technici	Category 1 and 2
3	Brady Boynton	PT12788	Oncology Pharmacy Technici	Category 1 and 2
4	Sharon Casey	PT04303	Oncology Pharmacy Technici	Category 1 and 2
5	Theodore Fullmer	PT17191	Oncology Pharmacy Technici	Category 1 and 2
6	Daniela Guajardo-Nunez	PT19479	Oncology Pharmacy Technici	Category 1 and 2
7	Amie Valencia	PT18248	Oncology Pharmacy Technici	Category 1 and 2
8	Noah Villanueva	PT28830	Oncology Pharmacy Technici	Category 1 and 2
9				
10				

General Information				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 1.5	Pharmacy compounds Category 1 compounded sterile products?	✔		
USP 797 Section 1.5	Pharmacy compounds Category 2 compounded sterile products?			
USP 797 Section 1.5	Pharmacy compounds Category 3 compounded sterile products?			

Personnel Training and Evaluation Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 2	Documentation is on file for each person who compounds sterile products or personnel who have direct oversight of compounding personnel that the person is competent and proficient to correctly perform all tasks related to sterile compounding and has received initial and ongoing training to establish and maintain their competency?	✔		
The following records for personnel are completed on an initial and every 12 month basis: General requirements				
USP 797 Section 2.1	Hand hygiene?	✔		
	Garbing?	✔		
	Cleaning and disinfection?	✔		
	Calculations, measuring, and mixing?	✔		
	Aseptic technique?	✔		
	Achieving and/or maintaining sterility and apyrogenecity?	✔		
	Use of equipment?	✔		
	Documentation of the compounding process?	✔		
	Principles of HEPA filtered unidirectional airflow within the ISO-5 environment?	✔		
	Proper use of primary engineering controls?	✔		
	Principles of movement of materials and personnel within the compounding area?	✔		
The following records for personnel are completed on an initial basis and then at an interval listed below: Garbing and GFT testing				
USP 797 Section 2.2	Successfully complete initial garbing competency evaluation of no fewer than 3 separate times? (successful completion for initial test is defined as zero cfu's for both hands)	✔		
USP 797 Section 2.2	Successfully complete ongoing garbing at least once every 6 months for personnel compounding Category 1 and Category 2 CSPs, and at least once every 3 months for personnel compounding Category 3 CSPs? (every 12 months for personnel who have direct oversight of compounding personnel) (successful completion for ongoing test is defined as <= 3cfu's for both hands)	✔		
USP 797 Section 2.3	If conducting gloved fingertip and thumb sampling in a CAI or CACI the samples are taken from the sterile gloves placed over the gloves attached to the unit?			✔
USP 797 Section 2.2	Documentation of failure and re-testing is maintained?	✔		
The following records for personnel are completed on an initial basis and then at an interval listed below: Media fill testing				
USP 797 Section 2.3	Successfully complete an initial aseptic manipulation evaluation which consists of a visual observation, media fill testing, gloved fingertip sampling listed in Section 2.2, and surface sampling of the direct compounding area?	✔		
	Successfully complete an ongoing aseptic manipulation evaluation which consists of a visual observation, media fill testing, gloved fingertip sampling listed in Section 2.2, and surface sampling of the direct compounding area. Completed every 6 months for personnel compounding Category 1 and Category 2 CSPs and every 3 months for personnel compounding Category 3 CSPs. Completed every 12 months for personnel who have direct oversight of compounding personnel?	✔		
	The media-fill test simulates the most difficult and challenging aseptic compounding procedures encountered by the compounding person?	✔		
USP 797 Section 2.3	Documentation of failure and re-testing is maintained?	✔		

Personal Hygiene and Garbing				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 3	Individuals that may have a higher risk of contaminating the CSP and the environment report these conditions to the designated person?	✔		
Personnel Preparation				
USP 797 Section 3.1	There is no food or drinks in the anteroom, buffer room, or segregated compounding areas?	✔		
USP 797 Section 3.1	Before entering a compounding area all personnel remove outer garments, remove all cosmetics, remove any exposed jewelry, don't wear headphones or earbuds, don't bring electronic devices that are not necessary for compounding into the area, keep nails clean and neatly trimmed, don't wear nail products, and wipe eyeglasses if worn?	✔		
USP 797 Section 3.1	The designated person documents any accommodations made for personnel?	✔		
Hand Hygiene				
USP 797 Section 3.2	Personnel wash hands and forearms up to the elbows with soap and water before initiating compounding activities?	✔		
USP 797 Section 3.2	Brushes are not used for hand hygiene?	✔		
USP 797 Section 3.2	Hand dryers are not used for hand hygiene?	✔		
USP 797 Section 3.2	A closed system of soap is readily available?	✔		
USP 797 Section 3.2	Debris is removed from underneath fingernails using a disposable nail cleaner?	✔		
USP 797 Section 3.2	Hands and forearms are washed for at least 30 seconds?	✔		
USP 797 Section 3.2	Hands and forearms are dried with low-lint disposable towels?	✔		
USP 797 Section 3.2	Hands are sanitized with an alcohol-based hand rub prior to donning sterile gloves?	✔		
USP 797 Section 3.2	Sterile gloves are donned in a classified room or SCA?	✔		
Garbing Requirements				
USP 797 Section 3.3	The order of garbing is documented in the facility's SOP's?	✔		
USP 797 Section 3.3	If hand hygiene is completed outside of a classified area, alcohol-based hand rub is used prior to donning garb?	✔		
USP 797 Section 3.3	Skin is not exposed inside the ISO Class 5 PEC?	✔		
USP 797 Section 3.3	The following minimum requirements for preparing Category 1 and Category 2 CSPs are met by the organization? Low-lint garment with sleeves that fits snugly around the wrists and is enclosed at the neck, low-lint covers for shoes, low-lint cover for head that covers the hair and ears, low-lint face mask, sterile powder-free gloves.	✔		
USP 797 Section 3.3	When compounding within a CAI or CACI sterile gloves are worn over gloves attached to the RABS sleeve?			✔
USP 797 Section 3.3	The only garb that is reused are gowns and only if compounding Category 1 and Category 2 CSPs? The gown may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination.	✔		
USP 797 Section 3.3	When compounding Category 3 CSPs the following additional garbing requirements are met in the buffer room? No exposed skin in the buffer room, all low-lint outer garb must be sterile, including the use of sterile sleeves when a CAI or CACI is used.			✔

Facilities and Engineering Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 4 – 4.1.2	The anteroom providing access to positive pressure buffer room meets at least ISO 8 classification?			✔
USP 797 Section 4 – 4.1.2	The anteroom providing access to negative pressure buffer room meets at least ISO 7 classification?			✔
USP 797 Section 4 – 4.1.2	Buffer room meets at least ISO 7 classification?			✔
USP 797 Section 4 – 4.1.2	Category 1, Category 2, and Category 3 CSPs are prepared in an ISO Class 5 or better PEC?	✔		
USP 797 Section 4 – 4.1.2	Pharmacy only compounds Category 1 CSPs and the PEC is placed in an unclassified area?	✔		
Facility Design and Environmental Controls				
USP 797 Section 4.2	The temperature and humidity are monitored and documented at least once daily or through continuous monitoring systems?	✔		
USP 797 Section 4.2	Free standing humidifiers/dehumidifiers and air conditioners are not used within the classified areas or within the perimeter of the SCA?	✔		
Types of SECs and Design				
USP 797 Section 4.2.1	Access to the SEC is restricted to authorized personnel and required materials?	✔		
USP 797 Section 4.2.1	The following are required for Cleanroom suites:			
USP 797 Section 4.2.1	Air supplied to the cleanroom suite is introduced through HEPA filters that are located in the ceiling of the buffer and anterooms?			✔
USP 797 Section 4.2.1	Air returns in the cleanroom suite are low on the wall?			✔
USP 797 Section 4.2.1	The classified rooms are equipped with a pressure differential monitoring system?			✔
USP 797 Section 4.2.1	If a pass-through is used both doors are never opened at the same time?			✔
USP 797 Section 4.2.1	Tacky mats are not placed within ISO-classified areas?			✔
USP 797 Section 4.2.1	The following are required for Segregated Compounding Areas:			
USP 797 Section 4.2.1	Only Category 1 CSPs are compounded in an SCA?	✔		
USP 797 Section 4.2.1	The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow?	✔		
USP 797 Section 4.2.1	The SCA is not located in a restroom, warehouse, or food preparation area?	✔		
The CSP Compounding Environment				
USP 797 Section 4.2.2	The PEC is certified to meet ISO Class 5 or better conditions during dynamic operating conditions?	✔		
USP 797 Section 4.2.2	Unidirectional airflow is maintained in the PEC?	✔		
USP 797 Section 4.2.2	HEPA-filtered air is supplied by the PEC at a velocity sufficient to sweep away particles from critical sites and maintain unidirectional airflow during operations?	✔		
Types of PECs and Placement				
USP 797 Section 4.2.3	Placement of the PEC allows for cleaning around the PEC?	✔		
USP 797 Section 4.2.3	PEC is placed in an ISO Class 7 positive pressure buffer room with an ISO Class 8 positive pressure anteroom for non-hazardous compounding of Category 2 and Category 3 CSPs?			✔
USP 797 Section 4.2.3	A dynamic airflow smoke pattern test is performed in the PEC initially and at least every 6 months thereafter?	✔		
USP 797 Section 4.2.3	Laminar Airflow Workbench (LAFW):			
USP 797 Section 4.2.3	LAFW is not used in the preparation of antineoplastics and/or API HDs?	✔		
USP 797 Section 4.2.3	LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow?	✔		
USP 797 Section 4.2.3	Integrated vertical laminar flow zone (IVLFZ):			
USP 797 Section 4.2.3	IVLFZ is a designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room? The unidirectional HEPA-filtered zone is separated from the ISO Class 7 area with a physical barrier?			✔

USP 797 Section 4.2.3	Both static and dynamic smoke studies are documented?	✔		
USP 797 Section 4.2.3	Class 2 biological safety cabinet (BSC):			
USP 797 Section 4.2.3	The exhaust air from the BSC is externally vented for preparation of antineoplastic and/or API HDs?	✔		
USP 797 Section 4.2.3	Restricted Access Barrier System (RABS): Examples include CAI and CACI			
USP 797 Section 4.2.3	The recovery time after opening the transfer chamber to achieve ISO Class 5 air quality is documented?			✔
Air Exchange Requirements				
USP 797 Section 4.2.4	ISO Class 7 room requirements:			
USP 797 Section 4.2.4	A minimum of 30 total HEPA filtered ACPH is supplied to ISO Class 7 rooms?			✔
USP 797 Section 4.2.4	At least 15 ACPH of the total air exchange in a room comes from the HVAC through HEPA filters located in the ceiling?			✔
USP 797 Section 4.2.4	The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH?			✔
USP 797 Section 4.2.4	If the PEC is used to meet the minimum total ACPH requirement then the PEC is not turned off except for maintenance?			✔
USP 797 Section 4.2.4	The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH is documented on the certification report?			✔
USP 797 Section 4.2.4	ISO Class 8 room requirements:			
USP 797 Section 4.2.4	A minimum of 20 total HEPA filtered ACPH is supplied to ISO Class 8 rooms?			✔
USP 797 Section 4.2.4	At least 15 ACPH of the total air exchange in a room comes from the HVAC through HEPA filters located in the ceiling?			✔
USP 797 Section 4.2.4	The total ACPH is documented on the certification report?			✔
Establishing and Maintaining Pressure Differentials				
USP 797 Section 4.2.5	Continuous differential positive pressure monitoring is performed?	✔		
USP 797 Section 4.2.5	In the clean-room suite a minimum differential positive pressure of 0.020-inch water column is maintained between each classified area?	✔		
USP 797 Section 4.2.5	FYI – No pressure differential is required between the SCA and the surrounding area			
USP 797 Section 4.2.5	The quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding occurs?	✔		
Facilities preparing Category 2 or Category 3 CSPs from non-sterile starting components must meet the following requirements				
USP 797 Section 4.2.6	Pre-sterilization procedures such as weighing and mixing are completed in an ISO Class 8 or better environment?			✔
USP 797 Section 4.2.6	CVE, BSC, or CACI used for pre-sterilization is certified at least every 6 months?			✔
USP 797 Section 4.2.6	Personnel are following the hygiene and garbing requirements during the pre-sterilization procedures?			✔
Creating Areas to Achieve Easily Cleanable Conditions				
USP 797 Section 4.3.1	Cleanroom Suite requirements:			
USP 797 Section 4.3.1	Surfaces are smooth, impervious, free from cracks and crevices, and non-shedding?	✔		
USP 797 Section 4.3.1	Junctions are sealed?	✔		
USP 797 Section 4.3.1	If ceilings contain inlaid panels, the panels are caulked around each panel to seal them to the support frame?			✔
USP 797 Section 4.3.1	Walls are constructed of or covered with durable material?	✔		
USP 797 Section 4.3.1	Panels are joined together and sealed to each other and the support structure?	✔		
USP 797 Section 4.3.1	Floors include coving to the sidewall or the junction between the floor and the wall are caulked?	✔		
USP 797 Section 4.3.1	The exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed?	✔		
USP 797 Section 4.3.1	All other penetrations through the ceiling or walls are sealed?	✔		

USP 797 Section 4.3.1	SCA requirements:			
USP 797 Section 4.3.1	All surfaces are clean, uncluttered, and dedicated to compounding?	✔		
Water Sources				
USP 797 Section 4.4	Surfaces of sink are cleaned and disinfected each day of use and a sporicidal agent is applied at least monthly?	✔		
USP 797 Section 4.4	If the sink is located outside of the anteroom then it is located in a clean space?			✔
USP 797 Section 4.4	The buffer room doesn't contain any plumbed water sources?			✔
USP 797 Section 4.4	The anteroom doesn't contain any floor drains?			✔
USP 797 Section 4.4	If utilizing a SCA design, the sink is placed at least 1 meter away from the PEC?	✔		
Placement and Movement of Materials				
USP 797 Section 4.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the classified areas or SCA?	✔		
USP 797 Section 4.5	There are no shipping cartons or other corrugated or uncoated cardboard allowed in the classified areas or SCA?	✔		
USP 797 Section 4.5	Carts used to transport into classified areas are constructed from nonporous materials with cleanable casters and wheels?	✔		
USP 797 Section 4.5	In the clean-room suite the carts are not moved from the dirty side to the clean side of the anteroom unless the entire cart, including the casters, are cleaned and disinfected?	✔		
USP 797 Section 4.5	Proper placement of equipment in a PEC is initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow?	✔		
USP 797 Section 4.5	The dynamic airflow smoke pattern test is repeated if equipment is placed in a different location?	✔		
USP 797 Section 4.5	Any items removed from the classified areas or SCA are disinfected before they are returned to the classified areas or the SCA?	✔		
USP 797 Section 4.5	Materials necessary for performing compounding activities that have been exposed in patient care and treatment areas are not allowed to enter anterooms, buffer rooms, or SCA unless they have been thoroughly cleaned and disinfected?	✔		

Certification and Recertification				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 5	Independent certification of the classified areas including the PEC are performed initially and recertification is performed at least every 6 months?	✔		
USP 797 Section 5	Certification includes airflow testing, HEPA filter integrity testing, total particle count testing, dynamic airflow smoke pattern testing, number of personnel present in each PEC and SEC during total particle count tests and dynamic airflow smoke pattern tests documented?	✔		
USP 797 Section 5	Classified areas are recertified if there are changes to the area such as redesign, construction, replacement, or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality?	✔		
USP 797 Section 5	All certification and recertification reports are reviewed by the designated person?	✔		
USP 797 Section 5	A corrective action plan is implemented and documented in response to any out-of-range result?	✔		
USP 797 Section 5	Data collected in response to corrective actions are reviewed to confirm that the actions taken have been effective?	✔		
Total Airborne Particle Sampling				
USP 797 Section 5.1	Total airborne particle count testing is conducted in all classified areas during dynamic operating conditions at least every 6 months?	✔		
USP 797 Section 5.1	Total airborne particle sampling sites are selected in all classified areas?	✔		

USP 797 Section 5.1	If levels measured during the total air sampling program exceed the criteria for the ISO classification of the areas sampled, a cause is investigated and corrective action taken and documented?	✔		

Microbiological Air and Surface Monitoring				
Citation	**Question**	**Yes**	**No**	**NA**
UPS 797 Section 6	A written procedure for microbiological air and surface monitoring has been developed and implemented?	✔		
UPS 797 Section 6	All microbiological air and surface monitoring procedures, the test results, and the corrective actions are documented?	✔		
UPS 797 Section 6	Data collected in response to corrective actions have been reviewed to confirm that the actions taken have been effective?	✔		
General Monitoring Requirements				
USP 797 Section 6.1	The microbiological air and surface monitoring program includes both viable impact volumetric particulate sampling and surface sampling?	✔		
USP 797 Section 6.1	Regular review of the sampling data is performed to detect trends and the results of the review are documented?	✔		
USP 797 Section 6.1	Microbiological air and surface monitoring is performed initially and then monitored according to the minimum frequencies outlined in USP 797?	✔		
USP 797 Section 6.1	Microbiological air and surface monitoring is conducted in all classified areas during dynamic operating conditions?	✔		
USP 797 Section 6.1	Sampling is performed in the following circumstance: In conjunction with the certification of new facilities or equipment, after any servicing of facilities or equipment, in response to identified problems, in response to identified trends, or in response to changes that could impact the sterile compounding environment?	✔		
USP 797 Section 6.1	Surface sampling is performed at the end of a compounding activity or shift, but before the area has been cleaned and disinfected?	✔		
USP 797 Section 6.1	All active air sampling devices are serviced and calibrated as recommended by the manufacturer?	✔		
Monitoring Air Quality For Viable Airborne Particles				
USP 797 Section 6.2	A monitoring program for viable airborne particles has been developed and implemented to assess microbiological air quality in all classified areas?	✔		
USP 797 Section 6.2.1	Volumetric active air sampling is conducted in all classified areas using an impaction device during dynamic conditions?	✔		
USP 797 Section 6.2.1	This test is performed at least every 6 months for locations compounding Category 1 and Category 2 CSPs?	✔		
USP 797 Section 6.2.1	This test is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs?			✔
USP 797 Section 6.2.1	Air sampling sites are selected in all classified areas.	✔		
USP 797 Section 6.2.2	A general microbiological growth media that supports the growth of bacteria and fungi is used?	✔		
USP 797 Section 6.2.2	Samples are incubated in an incubator at the temperatures listed in USP 797?	✔		
USP 797 Section 6.2.2	The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and the results are reviewed and documented?	✔		
USP 797 Section 6.2.2	The incubator is placed in a location outside the sterile compounding area?	✔		
USP 797 Section 6.2.3	If levels exceed the action levels described in USP 797 the cause is investigated and corrective action taken?	✔		
USP 797 Section 6.2.3	If levels exceed the action levels described in USP 797 then at attempt is made to identify any microorganisms recovered to the genus level?	✔		
USP 797 Section 6.2.3	If levels exceed the action levels the corrective action plan is documented and includes resampling of failed areas to confirm corrective action was successful?	✔		

Monitoring Surfaces for Viable Particles				
USP 797 Section 6.3.1	Surface sampling is performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected?	✔		
USP 797 Section 6.3.1	If compounding Category 1 and Category 2 CSPs the surface sampling of all classified areas and pass-through chambers connecting to classified areas are conducted at least monthly?	✔		
USP 797 Section 6.3.1	If compounding Category 3 CSPs, a surface sampling is performed of all classified areas and pass-through chambers connecting to classified areas is completed prior to assigning a BUD longer than the limits established in USP 797 and at least weekly on a regular scheduled basis regardless of the frequency of compounding Category 3 CSPs?			✔
USP 797 Section 6.3.1	Surface sampling is conducted within the PEC used to prepare Category 3 CSPs at the end of each batch before cleaning and disinfection occurs?			✔
USP 797 Section 6.3.2	Surface sampling media devices contain microbiological growth media for sampling flat surfaces are utilized?	✔		
USP 797 Section 6.3.2	After sampling the sampled area is cleaned and disinfected?	✔		
USP 797 Section 6.3.2	Samples are incubated in an incubator at the temperatures listed in USP 797?	✔		
USP 797 Section 6.3.2	If levels exceed the action levels described in USP 797 the cause is investigated and corrective action taken?	✔		
USP 797 Section 6.3.2	If levels exceed the action levels the corrective action plan is documented and includes resampling of failed areas to confirm corrective action was successful?	✔		

Cleaning, Disinfection, and Applying Sporicidal Disinfectants and Sterile 70% IPA				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 7	Surfaces are cleaned prior to being disinfected unless an EPA registered one-step disinfectant cleaner is used to accomplish both the cleaning and disinfecting?	✔		
USP 797 Section 7	Sporicidal agents are used monthly for entities compounding Category 1 and/or Category 2 CSPs?	✔		
USP 797 Section 7	Sporicidal agents are used weekly for entities compounding Category 3 CSPs?			✔
USP 797 Section 7	In a PEC, sterile 70% IPA is applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue?	✔		
USP 797 Section 7	Sterile 70% IPA is applied immediately before initiating compounding?	✔		
USP 797 Section 7	During compounding sterile 70% IPA is applied to the horizontal work surface of the PEC at least every 30 minutes?	✔		
USP 797 Section 7	Cleaning is performed in the direction of clean to dirty areas?	✔		
USP 797 Section 7	The pharmacy has SOP's related to their cleaning procedures?	✔		
USP 797 Section 7.1.1	All products used are allowed to dwell for the minimum contact time specified by the manufacturer?	✔		
USP 797 Section 7.1.1	Cleaning, disinfecting, and sporicidal agents used within the PEC are sterile?	✔		
USP 797 Section 7.1.1	If diluting cleaning products the water used is sterile?			✔
USP 797 Section 7.1.2	All cleaning and disinfecting supplies are low lint?	✔		
USP 797 Section 7.1.2	Cleaning and disinfecting supplies used in the PEC are sterile?	✔		
USP 797 Section 7.1.2	Disposable supplies are discarded after each cleaning activity?	✔		
USP 797 Section 7.1.2	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal?	✔		

Introducing Items Into the SEC and PEC				
Citation	**Question**	**Yes**	**No**	**NA**
Introducing Items Into the SEC				
USP 797 Section 8.1	Before any item is introduced into the clean side of the anteroom, placed into pass-through, or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA registered disinfectant, or sterile 70% IPS using low lint wipers by personnel wearing gloves?	✔		
Introducing Items Into the PEC				
USP 797 Section 8.2	Just before any item is introduced into the PEC it is wiped with sterile 70% IPA and allowed to dry before use?	✔		
Use of Sterile 70% IPA on Critical Sites within the PEC				
USP 797 Section 8.3	Critical sites are wiped with sterile 70% IPA in the PEC and allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules?	✔		

Equipment, Supplies, and Components				
Citation	**Question**	**Yes**	**No**	**NA**
Equipment				
USP 797 Section 9.1	Equipment brought into the classified areas are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low lint wipers?	✔		
USP 797 Section 9.1	Before using automated compounding devices or other similar equipment, the compounding personnel conduct an accuracy assessment before the first use and again each day the equipment is used?			✔
USP 797 Section 9.1	The daily record of the accuracy measurements are maintained?			✔
Supplies				
USP 797 Section 9.2	Supplies in direct contact with the CSP are sterile and depyrogenated?	✔		
Component Selection				
USP 797 Section 9.3.1	APIs comply with the criteria in the USP-NF monograph, if one exists, have a COA, and are obtained from an FDA-registered facility?			✔
Component Receipt				
USP 797 Section 9.3.2	The date of receipt by the compounding facility is clearly marked on each API or added substance package that lacks a vendor expiration date?			✔
	Packages of components that lack a vendor's expiration date are assigned a conservative expiration date, not to exceed 1 year after receipt by the compounding facility?			✔
Component Evaluation Before Use				
USP 797 Section 9.3.3	Compounding personnel ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date, and have been stored under appropriate conditions?	✔		
USP 797 Section 9.3.4	All components are handled and stored in a manner that prevents contamination, mix-up's, and deterioration?	✔		
USP 797 Section 9.3.4	Personnel monitor temperature in the area where components are stored at least once daily on days that the facility is open and the readings are documented or readily available from a continuous monitoring device?	✔		

Sterilization and Depyrogenation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for depyrogenation?			✔
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by filtration?			✔

USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by steam heat?			✔
USP 797 Section 10	Pharmacy follows all required guidelines listed in USP 797 for sterilization by dry heat?			✔

Master Formulations and Compounding Records				
Citation	**Question**	**Yes**	**No**	**NA**
Creating Master Formulation Records				
USP 797 Section 11.1	A master formulation record is created for CSPs prepared for more than 1 patient and for CSPs prepared from nonsterile ingredients?	✔		
USP 797 Section 11.1	The master formulation record is a detailed record of procedures that describes how the CSP is to be prepared?	✔		
USP 797 Section 11.1	Any changes or alterations to the MFR are approved and documented according to the facility's SOPs?	✔		
USP 797 Section 11.1	The pharmacy is following all of the requirements for MFR's outlined in USP 797?	✔		
Creating Compounding Records				
USP 797 Section 11.2	A compounding record is created for all CSPs for Category 1, Category 2, and Category 3. A CR is also created for immediate use CSPS's prepared for more than one patient?	✔		
USP 797 Section 11.2	The compounding record is stored electronically?	✔		
USP 797 Section 11.2	The pharmacy is following all of the requirements for CR's outlined in USP 797?	✔		

Release Inspection and Testing				
Citation	**Question**	**Yes**	**No**	**NA**
Visual Inspection				
USP 797 Section 12.1	At the completion of compounding, before release and dispensing, the CSP is visually inspected to determine whether the physical appearance of the CSP is as expected?	✔		
USP 797 Section 12.1	The CSP is visually inspected to confirm that the CSP and its labeling match the prescription or medication order?	✔		
USP 797 Section 12.1	The CSP is visually inspected for container-closure integrity?	✔		
Sterility Testing				
USP 797 Section 12.2	FYI – Sterility testing is not required for Category 1 CSPs			
USP 797 Section 12.2	If a Category 2 CSP is assigned a BUD that requires sterility testing and all Category 3 CSPs, the testing is performed according to USP 71 or a validated alternative method?			✔
USP 797 Section 12.2	The pharmacy is following all of the requirements for sterility testing outlined is USP 797?			✔
Bacterial Endotoxin Testing				
USP 797 Section 12.3	FYI – Category 1 injectable CSPs do not require testing for bacterial endotoxin			
USP 797 Section 12.3	Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility and Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested to ensure that they do not contain excessive bacterial endotoxins?			✔

Labeling				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 13	The pharmacy is following all of the labeling requirements as outlined is USP 797?	✔		
USP 797 Section 13	If the CSP is sent outside the facility in which it was compounded the label includes the contact information of the compounding facility?	✔		

Establishing Beyond-Use Dates				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 14.1	Each CSP states the date, or the hour and date, beyond which the preparation must not be used and must be discarded?	✔		
USP 797 Section 14.2.4	Once a CSP is thawed from a frozen state, the CSP is not refrozen?	✔		
USP 797 Section 14.3	The BUD does not exceed the shortest remaining expiration date of any of the commercially available starting components?	✔		
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 1 CSPs?	✔		
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 2 CSPs?			✔
USP 797 Sections 14.3	Pharmacy is performing sterility testing on Category 2 CSPs in order to extend BUDs?			✔
USP 797 Sections 14.3	Pharmacy is performing terminal sterilization on Category 2 CSPs?			✔
USP 797 Sections 14.3	Pharmacy is following USP 797 BUD guidelines for Category 3 CSPs?			✔
USP 797 Sections 14.3	Pharmacy is performing terminal sterilization on Category 3 CSPs?			✔
USP 797 Sections 14.4.1	Category 3 CSPs are not assigned a BUD longer than the limits established by USP 797?			✔
USP 797 Sections 14.4.3	The BUD assigned to a Category 3 CSP is supported by stability data obtained using a stability-indicating analytical method?			✔
USP 797 Sections 14.4.3	The Category 3 CSP is prepared according to the exact formulation from which the stability data is derived?			✔
USP 797 Sections 14.4.3	The Category 3 CSP is packaged and stored in a container closure of the same materials of composition as that used in the study?			✔
USP 797 Sections 14.4.3	If the Category 3 CSP is an injection or if it is an ophthalmic solution a particulate matter test is conducted once per formulation with acceptable results?			✔

Multiple Dose CSPs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 14.5	Multiple dose CSPs are prepared as a Category 2 or Category 3 CSP?			✔
USP 797 Section 14.5	An aqueous multiple dose CSP has passed antimicrobial effectiveness testing in accordance with USP Chapter 51?			✔
USP 797 Section 14.5	After a multiple dose container is initially entered or punctured, the multiple dose container is not used for longer than the assigned BUD or 28 days, whichever is shorter?	✔		

Use of Conventionally Manufactured Products as Components				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 15.1	If a single dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it is only used up to 12 hours after initial entry or puncture as long as the storage requirements during that 12 hour period are maintained?	✔		

USP 797 Section 15.1	Opened single dose ampules are not stored for any time period?	✔		

Use of CSPs as Components				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 16	The component CSP is assigned a BUD consistent with USP 797 and is stored under conditions for its assigned BUD when not in use?	✔		
USP 797 Section 16	The final CSP is assigned a BUD consistent with USP 797?	✔		
USP 797 Section 16.1	Multiple dose CSPs are stored under the conditions upon which its BUD is based?	✔		
USP 797 Section 16.2	When a compounded single dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original single dose CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based?	✔		
USP 797 Section 16.2	The component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter?	✔		

SOPs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 17	SOPs have been developed for CSPs and a designated person has ensured that they are appropriate and implemented?	✔		
USP 797 Section 17	SOPS are reviewed initially and at least every 12 months by the designated person?	✔		

Quality Assurance and Quality Control				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 18	The designated person has ensured that the facility has a formal, written QA and QC program?	✔		
USP 797 Section 18	The overall QA and QC program is reviewed at least once every 12 months by the designated person?	✔		
USP 797 Section 18.1	The designated person has created a documented recall process?	✔		
USP 797 Section 18.2	The facility has developed and implemented SOPs for handling complaints?	✔		
USP 797 Section 18.2	The designated person reviews all complaints?	✔		
USP 797 Section 18.2	A readily retrievable written or electronic record of each complaint is kept by the facility?	✔		
USP 797 Section 18.2	A record is kept including the findings of any investigation and any follow-up?	✔		
USP 797 Section 18.3	Adverse events potentially associated with the quality of CSPs are reported in accordance with the facility's SOPs?	✔		

CSP Handling, Storage, Packaging, Shipping, and Transport				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 19.1	A controlled temperature area is established and monitored to ensure that the temperature remains within the appropriate range for the CSP?	✔		
USP 797 Section 19.2	If the CSP is sensitive to light, light-resistant packaging material is used?	✔		

Documentation				
Citation	**Question**	**Yes**	**No**	**NA**
USP 797 Section 20	The compounding facility maintains written or electronic documentation to demonstrate compliance with the requirements of USP 797?	✔		

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	3/19/2025
Pharmacist Printed Name:	Maura O'Brien
Pharmacist Signature:	Maura O'Brien

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: need state 1st
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Ridley's Pharmacy #1144

Physical Address: 568 Spring Valley Ct

City: Spring Creek State: NV Zip: 89815

Mailing Address (if different from physical address): 621 Washington St S

City: Twin Falls State: ID Zip: 83301

Telephone: 775-738-9248 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 385-331-5000 Contact Email: toddrwise@shopridleys.com

Website: shopridleys.com

Nevada Business License # (if applicable) NV20151478694

Supervising/Managing Pharmacist Name (NRS 639.220): Scott Simpsoon

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 15727

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Wyoming

Parent Company (if any): _____

Corporation/Organization Name: Ridley's Family Markets, INC

Mailing Address: 621 Washington St S

City: Twin Falls State: ID Zip: 83301

Telephone: 801-358-3365 Email: toddrwise@shopridleys.com

Contact Person Name: Todd Wise

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Pharmacy (title) for Ridley's Family Markets, INC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Todd Wise

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/10/20

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Todd Wise hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director of Pharmacy (title) for Ridley's Pharmacy #1144 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 06th day of February, 20 25

Notary Public

NOTARY PUBLIC
SAMANTHA HERRERA
740353
MY COMMISSION EXPIRES
NOVEMBER 25, 2028
STATE OF UTAH

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Scott Simpson Pharmacist Registration #: 15727

Pharmacy Name: Ridley's Pharmacy #1144

Initial each statement below to indicate you have read and agree with the following:

x SAS — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

x SAS — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

x SAS — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

x SAS — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

x SAS — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	yes	✗
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	yes	✗

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
$1,000 fine, C.E. audit for 2 renewals	ALASKA	5/29/2009	2600-09-003

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott A Simpson — 2/10/2025

Original signature of Managing Pharmacist (copies or stamps not accepted) — Date

State of Nevada
County of Clark
This instrument was acknowledged before me on this 10 by Scott Simpson

Notary Public - State Of Nevada
COUNTY OF CLARK
LAYLAH LEWIS
My Appointment Expires
January 3, 2028
No. 24-5398-01

I, Scott A Simpsm 2/10/2025

Upon a C.E. audit in 2008, the Alaska Board of Pharmacy rejected several C.E. units, which included 13.5 units from the Oregon State Pharmacy Associations annual convention, which included members of the OR BOP in attendance. These C.E. units were deemed not approved by ACPE by the AK BOP.

As a result, I was fined $1,000.00 and placed on C.E. audits for 2 license renewal periods. I am currently not licensed in OR and AK and have not done so in several years.

Attached are copies of the fine and ruling.

Scott A Simpsm 2/10/2005

State of Nevada
County of Clark
This instrument was acknowledged before me on 2/10/25 by Scott Simpson

Notary Public - State Of Nevada
COUNTY OF CLARK
LAYLAH LEWIS
My Appointment Expires
January 3, 2028
No. 24-5398-01

STATE OF ALASKA
DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT
Division of Corporations, Business and Professional Licensing

Sarah Palin, Governor
Emil Notti, Commissioner

June 4, 2009

Via Certified Mail No. 7006 2150 0003 6570 4491; Copy via First Class Mail

Mr. Scott Simpson
[redacted]
Las Vegas, Nevada [redacted]

Re: Pharmacist License No. 1436

Dear Mr. Simpson:

On May 29, 2009, the Alaska Board of Pharmacy adopted the Consent Agreement, Decision and Order in Case Number 2600-09-003. Enclosed is a fully signed copy of the agreement as adopted.

Payment in the amount of $1,000.00 must be received within 90 days of the board's signature, or no later than August 27, 2009. This payment will be applied to the unsuspended portion of the civil fine in accordance with the agreement. Failure to pay the fine on time will result in the reinstatement of the full fine.

Additionally, this agreement includes the requirement for mandatory audit of your continuing education documentation as a condition to renew your license for two future renewal periods. You will not receive any additional notice requesting documentation with renewal applications subject to this requirement. Satisfactory documentation must be received and approved before your renewal applications will be processed. So, upon receiving your renewal applications for the new two licensing periods, I encourage you to submit it to the Division with your documentation as quickly as possible in order to allow the necessary time for the approval process to occur.

All of the other terms and conditions of this agreement remain in effect until the mandatory audit requirement has been met. Any violation of this agreement will result in the consequences outlined in Section F, Violation of Agreement, on Page 6 of the Agreement.

If you have any questions, please don't hesitate to contact me by phone at (907) 465-1673, by email at karen.wilke@alaska.gov, or by mail at the address below.

Best Wishes,

Karen Wilke

Karen Wilke
Paralegal

Enclosure: Consent Agreement, Decision and Order
cc: Jennifer Strickler, Chief
Sher Zinn, Licensing Examiner
Brian Howes, Acting Chief Investigator
Martha Mendez, Investigator

STATE OF ALASKA
DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT

Sarah Palin, Governor
Emil Notti, Commissioner

Division of Corporations, Business and Professional Licensing

January 30, 2009

VIA CERTIFIED MAIL 7001 1940 0007 9245 4276; Copy Via First Class Mail

Scott Simpson
[redacted]
Las Vegas, Nevada [redacted]

Re: Alaska Pharmacist License No. 1436

Dear Mr. Simpson:

Your Pharmacist license file has been referred to me for review of the audit of your continuing education compliance following your recent license renewal.

To renew your license for the July 1, 2008 through June 30, 2010 (2008-2010) period, you were required by Alaska Statute (AS) 08.80.165 to satisfy the continuing education requirements established by the Alaska Board of Pharmacy (Board) before renewal.

Your Biennial Pharmacist License Renewal for July 1, 2008 – June 30, 2010 (renewal application) was received by the Division of Corporations, Business and Professional Licensing (Division) on May 19, 2008. As part of that application and as required under 12 AAC 52.320, you completed the Statement of Compliance indicating that you had successfully completed 30 hours of continuing education between July 1, 2006 and June 30, 2008. Your signature on that renewal application, dated May 15, 2008, certified that the information furnished in the application was true and correct, and confirmed your understanding that if audited you would be required to provide documentation to verify your compliance. Your license was renewed for the 2008-2010 license period in reliance on this information, effective May 30, 2008.

Your renewal application was among those randomly selected for audit to monitor compliance with continuing education in accordance with 12 AAC 52.350 and 12 AAC 02.960. On August 20, 2008, you were sent a letter instructing you to provide proof of your completion of 30 hours of approved continuing education as certified on your renewal application.

In response, you have provided documentation of 17 total hours completed between July 1, 2006 and June 30, 2008, as follows.

CE completed between July 1, 2006 and June 30, 2008

Date Complete	Activity/Program/Course	Sponsor/Provider/Instructor	Contact Hours Claimed
12/19/07	Fraud, Waste & Abuse Policies & Procedures	Learn Something/ACPE	1.0
9/28/07	Use of Probiotics in the Management of Antibiotic Associated Diarrhea	ACPE	2.0
9/24/07	A Good Night's Rest – Helping the Patient With Insomnia	ACPE	2.0
9/24/07	A.M. Hypertension and Home BP Monitoring	ACPE	2.0

9/24/07	Optimizing the Use of a Dopamine Agonist in Parkinson's Disease	ACPE	2.0
9/24/07	Incorporating Adult Immunization Service into Community	ACPE	2.0
9/24/07	A Review of Federal Legislation Affecting Pharmacy Practice	ACPE	2.0
9/24/07	An Overview and Update of the Controlled Substances Act of 1970	ACPE	2.0
9/24/07	The Pharmacists Role in Breaking the Cycle of PMDD	ACPE	2.0

You also provided documentation of courses that are *not approved by the ACPE*, as follows: Washington State HIV/AIDS (7 Units) – June 6, 2008; Treating To Goal for Type 1 and 2 Diabetes – Overcoming Barriers to Insulin – 1.5 hours – June 13, 2007; 2007 Annual Convention – 13.5 hours – Oregon State Pharmacy Association; Advancing Pain Management in Oregon – 1/1/07 – Oregon Dept. of Human Svcs.

On October 21, 2008, licensing examiner Sher Zinn notified you that all continuing education must be approved by the ACPE in order to be accepted. This is required by 12 AAC52.340(a).

In response, you completed an additional 17 hours of ACPE accredited education as follows:

CE completed after June 30, 2008

Date Complete	Activity/Program/Course	Sponsor/Provider/Instructor	Contact Hours Claimed
10/31/08	Eradicating Lice: Myths and Facts	ACPE	1.5
10/31/08	Asthma Treatment Guidelines and Use of Inhalers	ACPE	2.0
10/31/08	10 Strategies to Reduce Medication Errors	ACPE	2.0
10/31/08	Don't Sweat It: Epidemiology, Pathophysiology, and Treatment of Hyperhidrosis	ACPE	2.0
10/31/08	Prevention and Treatment of the Common Cold in Adults	ACPE	2.0
11/1/08	Legal and Practical Aspects of the Professional's Apology	ACPE	1.5
11/1/08	Current and Emerging Treatments to Quell Cold and Canker Sores	ACPE	2.0
11/1/08	Cases in Cardiology: Complications Associated with Heparin Therapy	ACPE	1.5
11/1/08	Review of Nutritional Supplements for the Treatment of Cartilage Degeneration	ACPE	1.0
11/1/08	Motion Sickness: Calming the Waves of Upset	ACPE	1.5

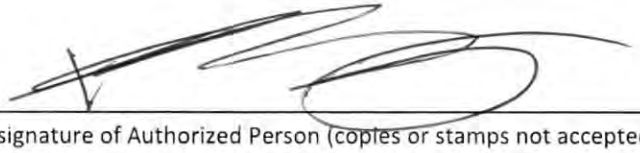
As discussed above, in order to comply with AS 08.80.165, the board-established continuing education requirements **must** have been completed by June 30, 2008. 12 AAC 52.320 requires completion of 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding licensing period. 12 AAC 52.340(a) is provided for you above, and does require ACPE approved courses.

Because you have taken courses that are not accepted under 12 AAC 52, you are not in compliance with the laws and regulations governing your license.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Todd Wise

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

01/10/2025

Date

Board Use Only	Date Received: 2/12/25	Amount: $500cc

A

Ridley's Family Markets Inc

TAX ID 453217322

List of Owners and Board Members

- Donald Mark Ridley – President (20% ownership) [redacted]
- Jerry Ridley – Owner (80% ownership) [redacted]
- Todd Wise – Director of Pharmacy (no Ownership) [redacted]

B

STATE OF WYOMING
Office of the Secretary of State

I, CHUCK GRAY, Secretary of State of the State of Wyoming, do hereby certify that according to the records of this office,

Ridley's Family Markets, Inc.

is a

Profit Corporation

formed or qualified under the laws of Wyoming did on **September 6, 2011**, comply with all applicable requirements of this office. Its period of duration is Perpetual. This entity has been assigned entity identification number **2011-000607899**.

This entity is in existence and in good standing in this office and has filed all annual reports and paid all annual license taxes to date, or is not yet required to file such annual reports; and has not filed Articles of Dissolution.

I have affixed hereto the Great Seal of the State of Wyoming and duly generated, executed, authenticated, issued, delivered and communicated this official certificate at Cheyenne, Wyoming on this 3rd day of December, 2024 at 3:42 PM. This certificate is assigned ID Number 078713732.

Chuck Gray

Secretary of State

Notice: A certificate issued electronically from the Wyoming Secretary of State's web site is immediately valid and effective. The validity of a certificate may be established by viewing the Certificate Confirmation screen of the Secretary of State's website https://wyobiz.wyo.gov and following the instructions displayed under Validate Certificate.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site _____

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 568 Spring Valley Court

City Spring Creek State NV Zip 89815

Mailing Address (if different from physical address) 621 Washington St. South Ste. 500

City Twin Falls State ID Zip 83301

Telephone 208-324-4633 Website _____

Licensing Company Email toddrwise@shopridleys.com

Section 2: Personal Information

First Donald Middle Mark Last Ridley

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Boise State ID Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St Josephs University		2000-2002	
Address	**City**	**State**	**Zip**
5600 City Avenue	Philadelphia	PA	19131
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Boise State University		1996-2000	
Address	**City**	**State**	**Zip**
1910 West University Drive	Boise	ID	83725
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Jerome High School		1992-1996	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	Zip
		Boise	ID	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Ridley's Family Markets			01-1992 - Current
Business Address	**City**	**State**	**Zip**
621 Washington St S	Twin Falls	ID	83301
Phone	**Title**		
208-324-4633 ext.10120			
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Ridley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-20-24

Date

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Ada

I, Donald Mark Ridley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-20-24

Date

Subscribed and Sworn to before me this 20 day of December.

Notary Public Signature

HAILEY LEWIS
NOTARY PUBLIC
STATE OF IDAHO
My Commission Expires 03/04/28
Comm. No. 20220476
(Seal)

(D)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Ridley's pharmacy #1144

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NA

Physical Address 568 Spring valley Ct

City Spring Creek State NV Zip 89815

Mailing Address (if different from physical address) 601 Washington St S

City Twin Falls State ID Zip 83301

Telephone 801 358 3365 Website

Licensing Company Email toddrw1@shopridleys.com

Section 2: Personal Information

First Jerry Middle Lee Last Ridley

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Eagle State ID Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pocatello High School		8/70 - 5/73	
Address	City	State	Zip
325 N. Arthur Ave	Pocatello	Id	83204
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/2023 - Now	[redacted]	Eagle	ID	[redacted]
6/2020 - 8/2021	[redacted]	Marathon	FL	[redacted]
5/2009 - 11/2020	[redacted]	Marathon	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Ridleys Family Markets			From - To (MM/YY – MM/YY): 3/1988 - Now	
Business Address: 621 Washington St. So. Ste 500	City: Twin Falls		State: ID	Zip: 83301
Phone: 208-324-4633	Title:			
Description of Duties: everything - Corp offic - owner				

Business Name: CJM LLLP			From - To (MM/YY – MM/YY): 12/2012 - Now	
Business Address: 621 Washington St So. Ste 500	City: Twin Falls		State: ID	Zip: 83301
Phone: 208-324-4633	Title: Partner			
Description of Duties: Partner				

Business Name: JCR LLP			From - To (MM/YY – MM/YY):	
Business Address: 378 W. Rivermont Lane	City: Eagle		State: ID	Zip: 83616
Phone: 208-320-2071	Title: Partner			
Description of Duties: Partner-Land				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jerry Lee Ridley
Print Name (First, Last)

Jerry Lee Ridley
Original Signature (electronic, copies or stamps not accepted)

12/18/24
Date

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Twin Falls

I, Jerry Ridley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jerry Ridley
Original Signature

12/18/24
Date

Subscribed and Sworn to before me this 18th day of December 2024.

Kara Gosnell
Notary Public Signature

KARA GOSNELL
Notary Public - State of Idaho
Commission Number 58468
My Commission Expires Oct 20, 2029

(Seal)

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Southeast Quality Pharmacy, LLC dba AnazaoHealth

Physical Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 813-882-4500 Toll Free # (NAC 639.708, NRS 639.23286): 800-723-7455

Fax: 866-823-5013 Contact Email: southeastlicensing@anazaohealth.com

Website: www.anazaohealth.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Calvin Buabeng

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21312

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Calvin Buabeng	NV Pharmacist Registration #: 21312
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): AnazaoHealth Corporation

Corporation/Organization Name: Southeast Quality Pharmacy, LLC dba AnazaoHealth

Mailing Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Telephone: 800-723-7455 Email: southeastlicensing@anazaohealth.com

Contact Person Name: Dana Nelson

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Southeast Quality Pharmacy, LLC dba A (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Hal Weaver

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Hal Weaver hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Southeast Quality Pharmacy, LLC dba AnazaoHe (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18th day of December, 2024

Notary Public

Notary Public State of Florida
Abbie J Oliver
My Commission HH 128199
Expires 05/10/2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hal Weaver

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Board Use Only	Date Received: 1/15/25	Amount: $500 CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Southeast Quality Pharmacy, LLC dba AnazaoHealth

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-723-7455 Toll Free # (NAC 639.708, NRS 639.23286): 800-723-7455

Fax: _____ Contact Email: southeastlicensing@anazaohealth.com

Website: www.anazaohealth.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Calvin Buabeng

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21312

Name of Designated Person(s) as defined by revised USP-797 guidelines: Calvin Buabeng

Email of Designated Person(s): southeastlicensing@anazaohealth.com

Telephone of Designated Person(s): 800-723-7455

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 10/25/2024

6. What is the frequency of the recertification for the ISO classified areas? Six Months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Daily

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Bremelanotide 10mg/ml
Estradiol Valerate 5mg/ml
Gonadorelin Acetate 0.2mg/ml
Hydromorphone (Preserved) 50mg/ml
Semaglutide 1mg/ml – L-Carnitine 100mg/ml
Semaglutide 5mg/ml – L-Carnitine 100mg/ml
Sermorelin Acetate 2mg/ml
Testosterone Cypionate in Grapeseed Oil (12.5mg, 50mg, 100mg, 200mg/ml)
Vitamin D in Olive Oil (1000 units and 10,000 units/ml)
Solutions used to refill implanted intrathecal pumps which contain varying patient-specific concentrations and combinations of the following drugs (Baclofen, Bupivacaine, Clonidine, Fentanyl, Hydromorphone, Ketamine, Morphine, and Prialt)

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Ste. 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 1(800) 393-1595

13. What is your procedure for visual inspection of compounded sterile products?
See attached WI-0031

14. How often do you perform glove fingertip and medial fill testing?
See attached SOP-0033

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
See attached SOP-0036

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
See attached SOP-0095

17. Who performs the sterile compounding process at your facility?

Pharmacy Technicians & Pharmacists.

18. Who is responsible and accountable for the sterile compounding process at your facility?
All pharmacy compounding personnel.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
See attached SOP-0043

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC		
2. Are you complying with all USP 800 guidelines?	■ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patient Information

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

See attached SOP-0040

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Baclofen
Bupivacaine HCL
Clonidine HCL
Morphine Sulfate
Hydromorphone HCL
Fentanyl Citrate
Sufentanil Citrate
Testosterone Cypionate
Sermorelin Acetate

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Every three Months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

See attached SOP-0093

5. What is the frequency for completing surface sampling? See attached SOP		
6. What is the frequency for using sporicidal agents? See attached SOP		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CALVIN B. BRABENG

Name of Person who Completed the Form

Pharmacy Manager

Title

Calvin Brabeng

Signature (copies or stamps not accepted)

1.8.25

Date

Board Use Only	Date Received: 1/15/25	Date Approved: _____	Approved By: _____

State of Florida
Department of State

I certify from the records of this office that SOUTHEAST QUALITY PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on February 27, 2024.

The document number of this limited liability company is L24000101396.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of November, 2024

Secretary of State

Tracking Number: 1844262082CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

INV355 - Community Pharmacy (New Business / Change of Owner)

File # 30149
Insp # 200958

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTHEAST QUALITY PHARMACY, LLC		09/18/2024
DOING BUSINESS AS		
ANAZAOHEALTH		
STREET ADDRESS	**TELEPHONE #**	**EXT**
5401 HANGAR COURT		
CITY	**COUNTY**	**STATE/ZIP**
TAMPA	HILLSBOROUGH	FL/33634

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

License # PS51078	Licensee Name Calvin Buabeng, PDM
License Type Registered Pharmacists	
License # PS36687	Licensee Name Dennis Davis
License Type Registered Pharmacists	
License # PS37652	Licensee Name Kim Yost
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

INV355 - Community Pharmacy (New Business / Change of Owner)

COMMUNITY REQUIREMENTS GENERAL SECTION

Rx Department is open for a minimum of 20 hours per week and signage stating the hours the pharmacy department is open. [64B16-28.1081, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-28.1035, F.A.C]	Yes
Private Consultation Area available. [64B16-28.1035, F.A.C]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary for the practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy has a designated Prescription Department manager with a current and active Florida license. [465.018, F.S.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16 -27.410(2)(a) F.A.C.] *AHCT-SOP-0003 "Pharmacy Technician Responsibilities"*	Yes
Continuous Quality Improvement Program described in Policy and Procedure manual [64B16-27.300 F.A.C.] [766.101(1)(a)(I) F.S.] *AHCT-SOP-0016 "Quality Assurance Program"*	Yes
Policy and Procedure to prevent the fraudulent dispensing or controlled substances. [465.022 (4) F.S] *AHCT-SOP-0006 "Order Entry and Prevention of Fraudulent Prescription Dispensing and Verification"*	Yes
Prescription Department is securable from unauthorized access. [64B16-28.109 F.A.C.]	Yes
All medications to be purchased from a Florida licensed wholesaler [499-F.S.] *Wholesaler: Amerisource Bergen, Fagron, Letco, Medisca*	Yes
The following rules have been reviewed with the applicant: 64B16-30.003, F.A.C. (Citations), 64B16-28.140(4) F.A.C. (Compounding Records), 64B16-28.1081, F.A.C. (Regulation of Daily Operating Hours; Commencement of Operation-s), 64B16-28.202, F.A.C (Closing of a Pharmacy)	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *AHCT-SOP-0043 "Prescription Delivery Procedure"*	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Remarks:

Pharmacy will be possibly be providing Central Fill Agreements at next inspection. The pharmacy will also have an SPE permit and an SSCP permit.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:9/18/2024

Representative:

Calvin Buabeng

Date:9/18/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File # 30155
Insp # 200826

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTHEAET QUALITY PHARMACY, LLC		11/21/2024
DOING BUSINESS AS ANAZAOHEALTH		
STREET ADDRESS 5401 HANGER COURT	**TELEPHONE #**	**EXT**
CITY TAMPA	**COUNTY** HILLSBOROUGH	**STATE/ZIP** FL/33634

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8 am to 3 pm
Monday Y	Monday Hours 8 am to 3 pm
Tuesday Y	Tuesday Hours 8 am to 3 pm
Wednesday N	Wednesday Hours 8 am to 3 pm
Thursday N	Thursday Hours CLOSED
Friday N	Friday Hours CLOSED
Saturday N	Saturday Hours CLOSED
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS571078	Licensee Name Calvin Buabeng
License Type Registered Pharmacists	
License # PS37652	Licensee Name Kimberly Yost
License Type Registered Pharmacists	
License # PS24514	Licensee Name Dennis Davis
License Type Registered Pharmacists	
License # RPT41839	Licensee Name William Miller
License Type Pharmacy Tech	
License # RPT105294	Licensee Name Amanda Provencher
License Type Pharmacy Tech	
License # RPT39341	Licensee Name Kellie Platt
License Type Pharmacy Tech	
License # RPT55852	Licensee Name Sean Eaton
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # Pending	

License Relations

RX DPT MGR/COR/POR

BUABENG, CALVIN BAAFI	License # 51078

INV797 - USP Sterile Compounding

A. INTRODUCTION & SCOPE – ALL CATEGORIES

Department of Health

SOUTHEAST QUALITY PHARMACY, LLC

AnazaoHealth

License Number: PH35316

Data As Of 1/30/2025

Profession	Pharmacy
License	PH35316
License Status	CLEAR/
Qualifications	Schedule II & III Central Fill Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	09/19/2024
Address of Record	5401 HANGAR COURT TAMPA, FL 33634
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
BUABENG, CALVIN BAAFI	RX DPT MGR/COR/POR	PHARMACIST	51078	08/02/2024

Click on the License Number to view License Details for that Practitioner

Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
SOUTHEAST QUALITY PHARMACY, LLC	STERILE COMPOUNDING	PHARMACY	35417	12/2/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Department of Health

SOUTHEAST QUALITY PHARMACY, LLC

AnazaoHealth

License Number: PH35417

Data As Of 1/30/2025

Profession	Pharmacy
License	PH35417
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	12/02/2024
Address of Record	5401 HANGAR COURT TAMPA, FL 33634
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
BUABENG, CALVIN BAAFI	RX DPT MGR/COR/POR	PHARMACIST	51078	08/12/2024
SOUTHEAST QUALITY PHARMACY, LLC	PHARMACY	PHARMACY	35316	12/02/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

AnazaoHealth®

Southeast Quality Pharmacy, LLC dba AnazaoHealth

Owners/Officers

AnazaoHealth Corporation
Authorized Member / 100% Owner of Southeast Quality Pharmacy, LLC
[redacted] Tampa, FL [redacted]

Hal Weaver
Authorized Manager of Southeast Quality Pharmacy, LLC
[redacted] Tampa, FL [redacted]

Andrew Pulido
Authorized Manager of Southeast Quality Pharmacy, LLC
[redacted] Austin, TX [redacted]

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
DECEMBER 5, 2024	**PH 35417**	**145520**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Special Sterile Compounding

EXPIRATION DATE: **FEBRUARY 28, 2027**

SOUTHEAST QUALITY PHARMACY, LLC
AnazaoHealth
5401 HANGAR COURT
TAMPA, FL - 33634

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
NOVEMBER 27, 2024	**PH 35411**	**145090**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Special P/E

EXPIRATION DATE: **FEBRUARY 28, 2027**

SOUTHEAST QUALITY PHARMACY, LLC
AnazaoHealth
5401 HANGAR COURT
TAMPA, FL - 33634

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Southeast Quality Pharmacy, LLC dba AnazaoHealth

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-723-7455 Website: www.anazaohealth.com

Licensing Company Email: southeastlicensing@anazaohealth.com

Section 2: Personal Information

First: Calvin Middle: Baafi Last: Buabeng

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Tampa State: FL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
University of Tampa			09/2018 - 08/2024
Address	**City**	**State**	**Zip**
401 W. Kennedy Blvd	Tampa	FL	33606
Diploma/Degree obtained, if any			
MBA			

School Name			From - To (MM/YY – MM/YY)
Long Island University			09/2008 - 05/2012
Address	**City**	**State**	**Zip**
1 University Plz	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Delaware County Community College			09/2006 - 08/2008
Address	**City**	**State**	**Zip**
901 Media Line Rd	Media	PA	19063
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/15 - Present	[redacted]	Brandon	FL	[redacted]
11/13 - 12/15		Tampa	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
AnazaoHealth Corporation			12/2013 - Present
Business Address	**City**	**State**	**Zip**
5710 Hoover Blvd	Tampa	FL	33511
Phone	**Title**		**Number of Employed Hours**
800.995.4363	Pharmacy Manager		40hrs weekly
Description of Duties			
Dispensing & Compounding,			

Business Name			From - To (MM/YY – MM/YY)
CVS			09/2012 - 11/2013
Business Address	**City**	**State**	**Zip**
100 E Lake Blvd	Mahopac	NY	10541
Phone	**Title**		**Number of Employed Hours**
			40 hrs per week
Description of Duties			
Dispensing			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Calvin Buabeng

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12·23·24

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Hillsborough

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-23-24

Date

Subscribed and Sworn to before me this 23 day of December 2024

Notary Public Signature

Notary Public State of Florida
Abbie J Oliver
My Commission HH 128199
Expires 05/10/2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Southeast Quality Pharmacy, LLC dba AnazaoHealth

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-723-7455 Website: www.anazaohealth.com

Licensing Company Email: southeastlicensing@anazaohealth.com

Section 2: Personal Information

First: Andrew Middle: _____ Last: Pulido

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Tampa State: FL Zip: 33634

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Vanderbuilt University		09/07-05/11	
Address	**City**	**State**	**Zip**
2301 Vanderbilt Place	Nashville	TN	37235
Diploma/Degree obtained, if any			
Bachelor of Arts, Economics			

School Name		From - To (MM/YY – MM/YY)	
Texas High School		09/03-06/07	
Address	**City**	**State**	**Zip**
4001 Summerhill Road	Texarkana	TN	78003
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Current	[redacted]	Austin	TX	[redacted]
06/21-04/23		Austin	TX	
06/18 - 05/21		Austin	TX	
12/17 - 06/18		Austin	TX	
01/13 - 11/17		Austin	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SEE ATTACHED RESUME			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Pulido

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Andrew Pulido, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2025

Date

Subscribed and Sworn to before me this 6th day of January, 2025

Notary Public Signature

KYLIE SHCHERBAKOV
Notary Public, State of Texas
Comm. Expires 10-07-2025
Notary ID 130929147

(Seal)

Andrew C. Pulido

[redacted]

Austin, TX

BACKGROUND

I am a dynamic, entrepreneurial leader with a proven track record of leading transformational growth across multiple businesses and complex multi-national operating environments in both private and publicly owned companies. I led the creation of a pharmaceutical start-up and then sold it to a global leader in the space for $70M between 2014-2018. Following the sale of our company, I achieved the earn-out period in full while simultaneously integrating with Fagron's existing business. After the earn-out was complete, I accepted a new role on the global executive leadership team at Fagron. In this capacity, as President of North America, I oversee all US Businesses and Subsidiaries, which include three key divisions. With full ownership and oversight for P&L, commercial, operational, quality, regulatory and financial functions, I have transformed Fagron's global business and the US segment over the past 3.5 years, positioning Fagron as a formidable market leader.

With focus on organic and non-organic strategic growth initiatives and culture, I was able to lead the rise in sales from $80M to $400M, accompanied by EBITDA growth from $12.5M to $85M. I've a proven track record of orchestrating successful strategic acquisitions, CapEx investments (including new factories & infrastructure), divestitures, and optimizing non-core business elements. Key achievements include transforming the Sterile Services business from $42M ($8M EBITDA) to $180M ($38.8M EBITDA) in three years, elevating our market placement to #2 in the industry, propelling our Brands & Essentials division from #6 to #2, and supporting the significant shift in market place of our Health and Wellness division from #5 to #2, growing from $56M ($14.5M EBITDA) to $115M ($29M EBITDA) in three years.

PROFESSIONAL EXPERIENCE

Fagron NV, Austin, TX **2018 - Present**

President, Fagron North America
2020 - Present

- As a part of the global Executive Leadership Team, as President of North America I oversee three key divisions across North America; Brands & Essentials, Sterile Services, and Health & Wellness pharmacy services. These companies and subsidiaries comprise of approximately 1,350 employees across 11 facilities.
- I am fully responsible for all strategy, business performance and global execution of North American business; with achievement of $400M combined revenue with $85M EBITDA.
- Key acquisitions, divestitures and exits in support of business growth and excellence are as follows:
  - Fresenius Kabi 503B Outsourcing Facility (2022)
    For an undisclosed sum, to increase capacity of IV bag production and secure Northeast geographical foothold for key customers (Sterile Services Division)
  - Letco Medical (2022)
    For $34M, acquisition of the #4 market player resulting in our movement to #2 market player in industry as a result of acquired market share via active pharmaceutical ingredients and supplies platforms for Fagron's customer base. (Brands & Essentials Division)
  - Fagron Consumer Healthcare CDMO Divestiture (2022)
    80% majority interest in Fagron Consumer Healthcare CDMO; For $6M to divest non-core business with a strategic reverse supply chain arrangement for key brands (Brands & Essentials Division)
  - US Compounding Inc Assets (2021) from Adamis Pharmaceuticals
    For $5M, to increase product range and customer access for key ophthalmic & hospital segments (Sterile Services Division)
  - GX Sciences (2020)
    For $4.9M, as entre to precision diagnostic testing as an innovative additional offering for our practitioners (Brands & Essentials Division)

President, Fagron Brands & Essentials US and Humco
2018 - 2020

- Along with the sale of Humco, I fully achieved the two year earn-out for Humco performance while successfully integrating with Fagron's existing business
- As President of Fagron's Brands & Essential and Humco divisions, I was responsible for all commercial and operational strategy and execution
- Resultant impact demonstrated significant revenue increase from $45M to $90M with EBITDA improvement from $4M to $20M

Humco, Texarkana, TX **2013 - 2018**

President, Global Pharmaceuticals
2015 – 2018

- Responsible for all strategy and execution of business
- Successfully positioned the company for sale from start up to $30M revenue run rate resulting in a $70M purchase by Fagron, a global market leader.

Vice President, Corporate Development
2013 – 2015

Bank of America Merrill Lynch Chicago, IL **2011 - 2013**

Global Investment Banking
2011 - 2013

BOARD OF DIRECTOR MEMBERSHIP

PharmaNobis, *a Signet Healthcare Partners & GMS Capital Partners Investment Portfolio Company* **2022 - Present**
Humco Holding Group **2013 - 2018**

EDUCATION

Vanderbilt University **2007 - 2011**
Bachelor of Arts, Economics, May 2011
Minor in Managerial Studies- Financial Economics and Corporate Strategy
Varsity Division 1A Tennis Team Member

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Southeast Quality Pharmacy, LLC dba AnazaoHealth

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 5401 Hangar Court

City: Tampa State: FL Zip: 33634

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-723-7455 Website: www.anazaohealth.com

Licensing Company Email: southeastlicensing@anazaohealth.com

Section 2: Personal Information

First: Hal Middle: James Last: Weaver

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Tampa State: FL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hal Weaver

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Hillsborough

I, Abbie J. Oliver, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date**

Subscribed and Sworn to before me this 18th day of December.

Notary Public Signature

Notary Public State of Florida
Abbie J Oliver
My Commission HH 128199
Expires 05/10/2025

(Seal)

[redacted]

PROFESSIONAL EXPERIENCE

Fagron Holdings USA, LLC

President Health and Wellness / AnazaoHealth **Aug 2020 to Present**

Responsible for leading AnazaoHealth Corporation and Health and Wellness for Fagron NA.

President Fagron NA **Oct 2018 to August 2020**

Responsible for leading the Fagron North America companies by creating, communicating and implementing the organization's vision, mission and overall direction.

AnazaoHealth Corporation *2002 to October 2018*

President **April 2016 to October 2018**

Responsible for AnazaoHealth Corporation

- Tampa (Corporate HQ)
  - 503a sterile and non-sterile pharmacy
  - Specialty Nuclear Pharmacy
- Las Vegas
  - 503b Outsourcing Facility

Vice President, Operations – Custom Pharmacy **2013 to March 2016**

Responsible for all Custom Pharmacy Operations

General Manager – Custom Pharmacy Division **2008 to 2013**

Responsible for Custom Pharmacy Division's daily operations, facility management and business development and growth. Current staff structure is comprised of pharmacy supervisors, pharmacists, pharmacy technicians, customer service and shipping personnel.

Brachytherapy Operations Manager **2004 to 2008**

Responsible for Brachytherapy Department's daily operations; teams were comprised of pharmacy supervisors, pharmacists, an engineer, quality assurance personnel, pharmacy technicians and customer service staff. Additional departmental responsibilities included continued improvement of quality management system, radiation safety and regulatory compliance, sales and marketing, budgeting and staffing.

Nuclear Pharmacy Supervisor **2002 to 2004**

Responsible for day-to-day operations of the Nuclear Pharmacy. Supervised staff of 17 employees comprised of technicians, quality assurance, shipping and customer service personnel. Responsible for training, developing and implementing quality assurance processes and high-level customer service support with large companies, Radiation Oncologists and Nuclear Physicists.

Micro-Connection of Tampa Bay, Inc ***1996 to 2006***

President and Owner

Owned and operated a family business that provided custom mailing services and IT support to small and mid-sized businesses in the Tampa Bay area. Services included management of private customer mailing lists, creation of USPS automation compatible mailings, sale of computer equipment, computer repair, network installations and support.

EDUCATION

University of Nevada, Las Vegas Masters of Business Administration	Las Vegas, Nevada 2012
University of South Florida, College of Business Administration Bachelor of Science in Management Information Systems	Tampa, Florida 2003
Hillsborough Community College Associate in Arts in Business Administration	Tampa, Florida 1996

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS4953940	02-29-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-09-2024

SOUTHEAST QUALITY PHARMACY, LLC DBA ANAZAOHEALTH
5401 HANGAR CT
TAMPA, FL 336345341

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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2,2N,3, 3N,4,5	RETAIL PHARMACY	12-09-2024

SOUTHEAST QUALITY PHARMACY, LLC DBA ANAZAOHEALTH
5401 HANGAR CT
TAMPA, FL 336345341

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Form DEA-223 (9/2016)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
SEPTEMBER 20, 2024	**PH 35316**	**143587**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2025**

SOUTHEAST QUALITY PHARMACY, LLC
AnazaoHealth
5401 HANGAR COURT
TAMPA, FL - 33634

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7141

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

12/10/2024

Work Order Item Number:	W2024121002492 - 4110380
Filing Number:	20244524438
Filing Type:	Initial List
Filing Date/Time:	12/10/2024 20:00:14 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E45244372024-3

Entity Name: SOUTHEAST QUALITY PHARMACY LLC

Entity Status: Active

Expiration Date: None

Commercial Registered Agent
C T CORPORATION SYSTEM**
701 S CARSON ST STE 200, Carson City, NV 89701, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

This copy expires on 06 Jan 2025 at 06:25:46 am. Document Effective Date: 25 Nov 2024

AnazaoHealth®

Section Name: **Training**	Procedure Name: **Media Fill for Sterile Compounding**
Procedure #: **AHCT-SOP-0033**	Revision: 10 Effective Date: 25 Nov 2024

1.0 Purpose

1.1 To establish a protocol followed by AnazaoHealth Pharmacists and Pharmacy Technicians involved in the compounding of Sterile Preparations in order to comply with Chapter USP <797>.

1.2 To verify and continuously monitor the quality of the aseptic technique of all individuals involved in compounding of sterile preparations.

1.3 To verify and continuously monitor the capability of the compounding environment and processes used to produce compounded sterile preparations for human use.

2.0 Scope

2.1 This applies to pharmacists and technicians performing (or supervising) sterile compounding at AnazaoHealth Tampa.

3.0 Responsibilities

3.1 The Pharmacy Manager, or designee, is responsible for ensuring that all affected employees receive training on this procedure and that procedures are adhered to.

4.0 Definitions

4.1 USP – United States Pharmacopeia
4.2 MFU – media fill unit
4.3 GFT – gloved fingertip and thumb
4.4 CSP – Compounded Sterile Preparation
4.5 DCA – Direct Compounding Area
4.6 PEC – Primary Engineering Control

5.0 Reference Documents

5.1 AHCT-FORM-0027 Garbing Competency and GFT Log
5.2 AHCT-FORM-0011 Training Acknowledgement Form
5.3 AHCT-FORM-0028 Aseptic Technique Competency
5.4 AHCT-FORM-0025 Media Fill Cleaning and Disinfecting Competency
5.5 AHCT-FORM-0022 Media Fill and GFT Log
5.6 AHCT-FORM-0017 Facility and Personnel Environmental Sampling Action Report
5.7 AHCT-WI-0041 Category 2 Media Fill
5.8 AHCT-WI-0042 Premix Bag Batch Media Fill
5.9 AHCT-WI-0043 Vial and Lyo Batch Media Fill
5.10 AHCT-WI-0082 Hazardous Drug Batch Media Fill
5.11 AHCT-FORM-0108 Hangar Ct Gowning Competency and GFT Log

6.0 Parameters

6.1 All pharmacists and technicians must complete and pass an initial Garbing Competency and GFT sampling no fewer than 3 separate times before an initial media fill process.

6.2 Performing aseptic technique or compounding verification is a critical product integrity monitor. It is imperative that all individuals involved in sterile product preparation comply with this procedure.

Printed on: 07 Jan 2025, 08:26:02 am; Printed by: KIMBERLY.YOST.

Section Name: **Training**	Procedure Name: **Media Fill for Sterile Compounding**
Procedure #: **AHCT-SOP-0033**	Revision: 10 Effective Date: 25 Nov 2024

6.3 Proper aseptic technique is evaluated by direct visual observation by the training specialist or designee and through process simulation testing. Process Simulation Testing utilizes a microbiological growth medium as a substitute for the usual components of an aseptically prepared preparation.

6.4 Employee media-fill evaluates production process techniques involved in the preparation of sterile products and can be used to detect and identify technical flaws or procedural concerns that could potentially compromise end product integrity through microbial contamination.

6.5 Non-sterile Tryptic Soy Broth (TSB) with color indicator is the microbiological medium employed in this process. The supply of TSB must be certified by the manufacturer to support microbial growth as a result of growth promotion tests.

6.6 Initial media fill testing must successfully be completed by all sterile compounding personnel (both pharmacists and technicians) prior to compounding sterile preparations.

6.7 The competency of the compounding personnel will be evaluated by direct observation for each occurrence and type of media fill process testing.

6.8 A Surface sample of the DCA inside the PEC will be taken immediately after the media fill.

6.9 A GFT sample inside the PEC will be taken immediately after a media fill.

6.9.1 For WI-0043, an additional GFT sample is taken in the transfer device after transfer is complete.

6.10 The preparation of MFU's of media may be performed during normal production hours, but in a separate area away from the CSPs being compounded.

6.10.1 Compounding personnel MUST NOT prepare MFUs in the PEC while also compounding sterile preparations.

6.11 The appropriate media fill must be completed and logged in to the online program, Simplifi SoleSource® in the required month for employees to perform compounding or supervising duties inside the cleanroom.

6.12 Media Fill work instructions are to be opened through Master Control or the current revision available in another format during the media fill process.

7.0 Initial Personnel Media Fill

7.1 All compounding and supervisors of compounding personnel who have passed initial Garbing and GFT sampling must complete hands on training in the training hoods to practice aseptic techniques specific to each media fill. This will be performed by the Trainers and documented on the Training Acknowledgement Form (FORM-0011).

7.2 Then complete the applicable initial media fill- completed two times (consecutive days are preferred, but if not possible, then within 5 working days). See work instructions:

7.2.1 AHCT-WI-0041 Category 2 Media Fill

7.2.2 AHCT-WI-0042 Premix Bag Batch Media Fill

7.2.3 AHCT-WI-0043 Vial and Lyo Batch Media Fill

7.2.4 AHCT-WI-0082 Hazardous Drug Batch Media Fill

7.3 Initial media fill includes completing 1 GFT sample and a surface sample in the PEC immediately following the media fill (sample taken once within the 2 times of testing).

7.4 AHCT-FORM-0022 Media Fill and GFT Log will be used to document all Media Fill testing, GFT (1 day), surface sampling (1 day), and bubble point information for each day and type of media fill process completed.

7.5 Additionally, the competency of the compounding personnel will be evaluated by direct observation for each time and type of media fill process testing, using the Competency Assessment forms:

7.5.1 Aseptic Technique (AHCT-FORM-0028)

7.5.2 Media Fill Cleaning and Disinfecting (AHCT-FORM-0025)

Section Name: **Training**	Procedure Name: **Media Fill for Sterile Compounding**
Procedure #: **AHCT-SOP-0033**	Revision: 10 Effective Date: 25 Nov 2024

7.6 Only upon completion and successful incubation of all MFUs, is a compounding employee qualified to compound sterile preparations for human use.

8.0 Ongoing Media Fill

8.1 After passing the initial media fill, all compounding and supervisors of compounding personnel must successfully complete the applicable ongoing media fill at least every 3 months. Media fill testing must be performed and completed no later than the last day of the third month from the date the previous media fill was initiated. See work instructions:
- 8.1.1 AHCT-WI-41 Category 2 Media Fill
- 8.1.2 AHCT-WI-0042 Premix Bag Batch Media Fill
- 8.1.3 AHCT-WI-0043 Vial and Lyo Batch Media Fill
- 8.1.4 AHCT-WI-0082 Hazardous Drug Batch Media Fill

8.2 The media fill includes completing 1 GFT sample and a surface sample in the PEC immediately following the media fill.

8.3 AHCT-FORM-0022 Media Fill and GFT Log will be used to document all Media Fill testing, GFT, surface sampling and bubble point information for each type of media fill process completed.

8.4 Additionally, the competency of the compounding personnel will be evaluated by direct observation for each type of media testing occurrence, using the Competency Assessment forms:
- 8.4.1 Aseptic Technique (AHCT-FORM-0028)
- 8.4.2 Media Fill Cleaning and Disinfecting (AHCT-FORM-0025)

8.5 **Media Fill Inspection Information**
- 8.5.1 Each MFU will be visually inspected periodically and on Day 14 (final day of incubation). Any person, including the person who prepared the MFU may conduct MFU inspection, except on the last day of incubation (Day 14). Someone else must perform the Day 14 inspection other than the person who prepared the MFU's. The Microbiologist or designee will perform the final inspection for any signs of turbidity or color change prior to proper disposal of MFU's. Results are recorded on the appropriate Media Fill and GFT Log.
- 8.5.2 Any positive test results will immediately be brought to the attention of the Pharmacy Manager and Microbiology Supervisor or designee, and investigative action will be taken to determine the source of any contamination and appropriate corrective action will ensue (using AHCT-FORM-0017 Facility and Personnel EM Sampling Action Report).
- 8.5.3 The individual with the positive MFU will immediately be removed from compounding the preparations represented by the media fill.
- 8.5.4 The individual experiencing the positive MFU must repeat the media fill.
- 8.5.5 Once passing results are obtained, the individual can resume compounding those preparations.
  - 8.5.5.1 Note: A control that is positive for growth is considered a "Pass" on the Media Fill and GFT Log.
  - 8.5.5.2 When the non-sterile TSB Powder w/ Indicator is used, growth is present (positive) when the solution turns yellow or when turbidity is present.
- 8.5.6 All MFU's with growth must be carefully inspected for leaks (i.e., from defective seals, pinholes, cracked seams).

8.6 **Documentation**
- 8.6.1 All media fill results will be recorded on the Media Fill and GFT Log (AHCT-FORM-0022). These data sheets should be filed in chronological order in Document Control.

Section Name: **Training**	Procedure Name: **Media Fill for Sterile Compounding**
Procedure #: **AHCT-SOP-0033**	Revision: 10 Effective Date: 25 Nov 2024

8.6.2 The compounding employees will be evaluated via the Competency Assessment for Aseptic Technique (AHCT-FORM-0028) and Cleaning and Disinfecting (AHCT-FORM-0025) during a media fill testing occurrence.

8.6.3 Forms will be reviewed and signed by the Microbiology Supervisor or designee (Pharmacy Manager, Pharmacy Supervisor, or QA Manager)

8.7 **Operational Review**

8.7.1 It is the responsibility of the Pharmacy Manager to ensure that compliance to this media fill for sterile compounding occurs, and that all data is tracked as a part of a comprehensive facility quality assurance program.

Date	Name	Action
8/4/2016	K. Yost	Created AHCT-SOP-0033 from the general sections that apply to all media fills from P-402.2 and P-402.3; updated signature lines
9/8/2016	K. Yost	Added 4.5, 5.7, 5.9, 5.10 and 5.15; updated 6.10.1 to "AHCT-WI-0039"; added "AHCT-WI-0040" and "AHCT-WI-0082" to 6.11.1 all based on the new WI media fills
11/2/2017	K. Yost	Added 5.15; added "media Fill" to 6.6.3; 6.11.1.4; 6.12.2.4; added 6.10; added wording to 6.13.5.2; updated signature lines
1/4/2019	K. Yost	Grammar correction in 6.3 and 6.5; updated wording in 6.8, 6.11.1, 6.11.2, 6.12.1, 6.13.1, 6.14.1
07/22/2019	C.Buabeng	8.1 Updating 6.7 to remove the word "sterile." and deleting 6.8 – *"Non-sterile media will be reconstituted outside of the ISO 7 area and introduced into the clean room only when no active compounding is occurring in that cleanroom."*
3/2/2020	K. Yost	Eliminated reference to AHCT-WI-0040 Pain Management Media Fill – Ongoing in section 5.0 and 6.11.1; added detail to "consecutive days" statement in 6.10.1
6/30/2021	K. Yost/ S. Patterson	Updated forms in section 5.0; updated 6.11.1 from "twice a year" to "every 6 months"; updated forms in 6.13.1
1/11/2022	S. Patterson	Updated all Media fill WI titles and numbers. Added detailed instructions to initial and process verification sections 7.0 and 8.0. Updated content throughout.
10/31/2022	S. Patterson	Removal of reference to form AHCT-FORM-0023 throughout SOP.
10/20/2023	K. Yost	Updated FORM-0027 name throughout; updated media fill names throughout; added surface sample and GFT requirement after each media fill throughout; added 6.9.1; added hands on training requirement 7.1; changed requirement to every 3 months for ongoing media fills in 8.1; added 8.6.3
11/09/2023	T.Zabinski	Added 6.12 Media Fill work instructions requirement.
11/7/2024	K. Yost	Added reference 5.11 FORM-0108 Hangar Ct Gowning Competency and GFT log; Updated header with Procedure

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Document Number: AHCT-SOP-0033

Document Title: Media Fill for Sterile Compounding

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Author: KIMBERLY.YOST	Previous Number: P-402
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SOP-0033 Media Fill for Sterile Compounding

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	07 Nov 2024, 11:28:18 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	11 Nov 2024, 09:38:43 AM	Approved

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Section Name: **Training**	Procedure Name: **Orientation, Training and Competency Evaluation of Sterile Compounding Personnel**
Procedure #: **AHCT-SOP-0036**	Revision: **7** Effective Date: 12 Sep 2024

1.0 Purpose

1.1 The purpose of this procedure is to provide a consistent process and mechanisms to measure and document the acquired skill sets necessary to operate the equipment and perform processes required by pharmacy operations to compound sterile preparations.

2.0 Scope

2.1 This applies to pharmacists and sterile compounding technicians at AnazaoHealth Tampa.

3.0 Responsibilities

3.1 Pharmacy Manager, in coordination with his/her designee, is responsible for ensuring that all applicable employees receive training on this procedure and that procedures are adhered to.

4.0 Definitions

4.1 GFT – Gloved Fingertip and Thumb

4.2 SOP- Standard Operating Procedures

4.3 WI – Work Instructions

4.4 TSHP – Texas Society of Health System Pharmacists

5.0 Reference Documents

5.1 AHCT-FORM-0027 Garbing Competency and GFT Log

5.2 AHCT-FORM-0028 Aseptic Technique Competency

5.3 AHCT-FORM-0025 Media Fill Cleaning and Disinfecting Competency

5.4 AHCT-FORM-0029 Cleaning and Disinfecting Competency

5.5 http://www.criticalpoint-lms.com/ - Critical Point Training

5.6 https://fagron.mastercontrol.com – MasterControl Training

5.7 SImplifi SoleSource® - Electronic logging system

5.8 AHCT-FORM-0011 Training Acknowledgement form

5.9 AHCT-FORM-0017 Facility and Personnel Environmental Monitoring Investigation

5.10 AHCT-SOP-0033 Media Fill for Sterile Compounding

5.11 AHCT-FORM-0022 Media Fill and GFT Log

5.12 AHCT-WI-0026 Gloved Fingertip Sampling

5.13 AHCT-SOP-0034 Hand Hygiene and Garbing Procedure

5.14 AHCT-FORM-0082 Sterile Compounding Quiz

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5.15 AHCT-SOP-0094 Sterile Gowning Procedure

6.0 Parameters

6.1 The orientation, training and competency evaluation of sterile compounding personnel are designed to ensure that staff are adequately skilled, educated, instructed, and trained to correctly perform and document the critical activities in their sterile compounding duties.

6.2 Each employee will receive an orientation to the company and to their specific job role performed by the department manager or his/her designee. Didactic training as well as hands-on practical training and mentorship will be done by the designated trainer.

6.3 All pharmacists and technicians involved in the compounding/supervising of sterile preparations are required to complete the following:

6.3.1 Didactic coursework completed annually and/or as needed (i.e., Critical Point (797 and 800 modules) and MasterControl for SOPs and WIs).

6.3.2 Sterile Compounding quiz (AHCT-FORM-0082) to include calculations, conversions, and mixing completed annually with review of incorrect answers.

6.3.3 Practical skill assessments through competency evaluations completed at least annually and/or as needed (i.e., Cleaning and Disinfecting, Automated Compounding Devices)

6.3.4 Hands on training performed in training hoods completed prior to a new media fill.

6.3.5 Garbing with GFT sampling and media-fill testing with GFT sampling must be completed initially and then at least every 3 months. (AHCT-SOP-0034 Hand Hygiene and Garbing Procedure (or SOP-0094 Sterile Gowning Procedure), AHCT-WI-0026 Gloved Fingertip Sampling, AHCT-SOP-0033 Media Fill for Sterile Compounding).

6.3.6 All sterile compounding technicians must complete a National Sterile Compounding Training course through Texas Society of Health-System Pharmacists (TSHP) and receive a 40.0-hour statement of continuing pharmacy education credit to be put in employee training folder.

6.4 Pharmacy Support staff and General Pharmacy Technicians not involved in compounding are required to complete the following:

6.4.1 Didactic coursework completed annually and/or as needed (i.e., Critical Point (select 797 and 800 modules) and MasterControl for SOPs and WIs).

6.4.2 Practical skill assessments through competency evaluations completed at least annually (i.e. Cleaning and Disinfecting, Garbing and GFT sampling, Use of Autoclave, Use of Dry Heat Ovens)

6.5 Personnel who fail written or media-fill tests, will be reinstructed and reevaluated by the designated trainer to ensure correction to all aseptic processes as well as demonstrate the ability to pass repeated written and/or media-fill tests.

6.6 As new processes and equipment are introduced at the compounding facility, employees require training in order to properly use such new equipment or processes. Employees are required to demonstrate knowledge and skill in select procedures or tasks before they can independently perform those procedures in real life production.

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Section Name: **Training**	Procedure Name: Orientation, Training and Competency Evaluation of Sterile Compounding Personnel
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6.7 The Pharmacy Manager or his/her designee must observe all newly learned skills or procedures of staff to ensure their ability to demonstrate the skill/knowledge independently.

6.8 The orientation and training program must also include knowledge and ability to perform the following as applicable according to specific job code description, but is not limited to:

6.8.1 An orientation to pharmacy activities.

6.8.2 An overview of facility activities of other departments.

6.8.3 View demonstration of the processing of medications.

6.8.4 Materials Staging

6.8.5 Facility Cleaning and Disinfection

6.8.6 Environmental Sampling

6.8.7 Information about viable and non-viable particulate and microbial contamination.

6.8.8 Use of Primary and Secondary Engineering Controls

6.8.9 Pressure Gradient Monitoring

6.8.10 Temperature and Humidity Monitoring

6.8.11 Final Release Checks

6.8.12 Labeling

6.8.13 CSP Packaging for Delivery

6.8.14 Handling Hazardous Drugs

6.9 All staff must demonstrate a thorough understanding of completing and using all company forms and electronic logging system (e.g., Simplifi SoleSource®).

6.10 All staff must participate in intradepartmental visits/meetings as needed.

6.11 Any change in job code is communicated via email to Document Control and QA to ensure proper training is assigned.

7.0 Documentation

7.1 All occurrences of training whether during initial orientation or ongoing training must be documented as follows:

7.1.1 Training documentation for pharmacists and pharmacy technicians shall be kept in Document Control.

7.1.2 Appropriate Simplifi SoleSource® competencies assigned and completed.

7.1.3 Media-fill testing with GFT sampling must be documented on the appropriate Media-Fill and GFT Log (AHCT-FORM-0022).

7.1.4 Hand Hygiene and Garbing with GFT sampling must be documented on the appropriate Garbing Competency and GFT Log (AHCT-FORM-0027).

7.1.5 Competencies must be documented on the appropriate assessment forms (i.e., AHCT-FORM-0022, AHCT-FORM-0025, AHCT-FORM-0027, AHCT-FORM-0028, AHCT-FORM-0029).

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7.1.6 A failed Garbing competency, Media-Fill Testing, and/or GFT sampling, must be documented on the Facility and Personnel Environmental Monitoring Investigation (AHCT-FORM-0017).

7.1.7 Critical Point - printed transcripts.

7.1.8 TSHP Training Course - printed certificate of completion.

7.1.9 Signed Hazardous Drug Risk Acknowledgement (AHCT-FORM-0030).

7.1.10 The Training Acknowledgement Form (AHCT-FORM-0011) must be used to document instances of training not documented elsewhere.

Date	Name	Action
10/23/2012	K. Yost	Updated format, header, added signature lines; added SOP 9.4 to nuclear training records
9/17/2013	K. Yost	Added 5.11, 7.5.1.10 and 7.5.2.9 Cleaning and Disinfecting Form; added detail to 4.3
	J. Stark	Updated 3.1, Training records needed under 7.5, signature lines; Added 7.5.2
3/24/15	N. Benson	Updated language in 2.1, 3.1, 4.2, 4.3, 5.4, 6.1, 6.3, 7.1, 7.4 and 7.5; removed 6.4; updated language in 6.5.2, 6.5.8 and 6.5.10 (6.5 is now 6.4); removed 6.5.12, 7.5.1, 7.5.2, 7.5.3, 7.5.4 and 7.5.5; updated signature section; added section 7.0 information from P-101 to section 7 of policy.
4/2/15	N. Benson	Edited language in 6.1, 7.1, 7.1.1, 7.1.2 and 7.1.3.
2/23/2017	K. Yost	Updated format and signature lines; updated section 5.0 and added 5.3, 5.10-5.13; added form numbers to 7.2 and 7.5
7/5/2018	K. Yost	Updated title in 5.7 and 7.3; added 6.9.5.13; updated signature lines
11/14/2019	K. Yost	Updated title to include "Sterile Compounding"; inserted "sterile" throughout when referring to type of compounding; updated 6.3 to remove annual media fill for low/medium risk; removed storage location of non-pharmacy staff training documents; removed signature lines
12/29/2020	K. Yost	Removed references to Radioactive Media Fill Results Log; updated 5.12 and 5.13; added 6.8.13 regarding changes in job code
1/17/2022	S. Patterson	Updated Reference Documents section 5.0. Added 6.4 TSHP course training. Updated content throughout.
10/31/2022	S. Patterson	Removal of reference to form AHCT-FORM-0023 throughout SOP.
8/28/2023	K. Yost	Added 4.1-4.4, updated form names in 5.1 and 5.11; added detail to 6.3.1-6.3.5; added section 6.4; eliminated some duplicate topics in section 6.8; added 7.1.4
6/18/24	K. Yost	Added reference 5.15
8/28/24	K. Yost	6.3.5 Added reference to SOP-0094; updated header to "procedure"

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Document Number: AHCT-SOP-0036

Document Title: Orientation, Training and Competency Evaluation of Sterile Compounding Personnel

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Author: KIMBERLY.YOST	Previous Number: P-410
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SOP-0036 Orientation, Training and Competency Evaluation of Sterile Compounding Personnel

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	29 Aug 2024, 07:28:15 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	29 Aug 2024, 07:43:15 AM	Approved

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Section Name: **Training**	Procedure Name: **Hazardous Drug Employee Training and Safety Program**
Procedure #: **AHCT-SOP-0040**	Revision: 9 Effective Date: 14 Oct 2024

1.0 Purpose

1.1 HDs will be stored, handled, prepared, transported, and disposed of only under conditions that protect healthcare workers.

1.2 An HD safety program that incorporates administrative, engineering and work practice controls is developed and maintained in order to provide maximum protection to healthcare workers.

1.3 Any personnel who may come in contact with HDs during the normal course of their job duties will receive training on HD handling that is specific to their job duties. Personnel who may not be involved in compounding but may be expected to participate in hazardous drug inventory receiving, stocking, transport, or cleaning of areas associated with hazardous drug preparation must also receive training prior to performing those activities.

2.0 Scope

2.1 The scope of this procedure is limited to individuals that may come in contact with HDs defined as hazardous by NIOSH or by AnazaoHealth.

2.2 This procedure governs worker and environmental safeguards as well as employee training and competency evaluation required relative to all aspects NIOSH designated hazardous drug handling, storage, compounding, transport, and disposal.

3.0 Responsibilities

3.1 The Pharmacy Manager or designee is responsible for ensuring that all affected employees receive training on this procedure and that procedures are adhered to.

4.0 Definitions

4.1 HD – hazardous drug

4.2 SDS – Safety Data Sheet

4.3 NIOSH – National Institute for Occupational Safety and Health

4.4 BSC – Biological Safety Cabinet

4.5 CSTD – Closed System Transfer Device

4.6 SRT – Spill Response Team

4.7 ACPH – Air changes per hour

4.8 PEC – Primary Engineering Control

4.9 SEC – Secondary Engineering Control

4.10 PPE - Personal Protective Equipment

5.0 Reference Documents

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Section Name: **Training**	Procedure Name: **Hazardous Drug Employee Training and Safety Program**
Procedure #: **AHCT-SOP-0040**	Revision: 9 Effective Date: 14 Oct 2024

5.1 Occupational Safety & Health Administration, U.S. Department of Labor Technical Manual (20 Jan 1999). *CONTROLLING OCCUPATIONAL EXPOSURE TO HAZARDOUS DRUGS.*

5.2 Hazardous Drug Compounding Training on Critical Point, LLC found at https://www.criticalpoint-lms.com/

5.3 AHCT-FORM-0030 Hazardous Drug Risk Acknowledgement Form

5.4 AHCT-FORM-0031 Hazardous Drug Spill Report Form

5.5 Current NIOSH List - http://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

5.6 AHCT-FORM-0071 NIOSH List of Antineoplastics and Other Hazardous Drugs

5.7 AHCT-SOP-0044 Pharmacy Waste Plan

5.8 AHCT-WI-0028 Respirator Fitting Instructions – N95

5.9 AHCT-FORM-0087 Respirator Training and Fit Testing Report

5.10 AHCT-WI-0123 HD Spill Management

5.11 AHCT-FORM-0098 Accident Report

6.0 Procedures

6.1 Administrative Controls

6.1.1 A list of HDs handled at the pharmacy will be posted in the pharmacy, reviewed, and revised annually, and communicated to staff in training programs (FORM-0071).

6.1.2 Storage areas containing HDs must be indicated with distinctive labels.

6.1.2.1 Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs (if applicable) may be stored with other inventory.

6.1.3 SDSs (formerly known as Material Safety Data Sheets (MSDS)) will be immediately available for every drug on the pharmacy HD use list.

6.1.3.1 These are located in AHPS>Tools>Add/Edit>Common Inventory>(enter ingredient name)>Right click on correct ingredient>Edit Common Inventory Record>Documents>Safety Data Sheet>View Selected File.

6.1.3.2 If a new drug/ingredient is received, give it to a Lead Pharmacist or designee for review for appropriate label information.

6.1.4 Procedures and forms will be reviewed and revised annually to reflect relevant local, state, and federal regulatory requirements as well as professional practice standards.

6.1.5 Whenever possible, HD staging and compounding should be limited to as few compounders as possible based on the workload to reduce the exposure across staff.

6.1.6 Staff can be rotated through HD compounding duties.

6.1.7 HD Employee Training

Section Name: **Training**	Procedure Name: **Hazardous Drug Employee Training and Safety Program**
Procedure #: **AHCT-SOP-0040**	Revision: 9 Effective Date: 14 Oct 2024

6.1.7.1 All employees that handle HDs must successfully complete training that includes Pharmacy Waste Plan (AHCT-SOP-0044) and Hazardous Drug Compounding Training on Critical Point, LLC which includes the following:

6.1.7.1.1 Overview of HDs including the NIOSH properties of hazardous drugs

6.1.7.1.2 Spill containment and cleanup

6.1.7.1.3 Treatment of personnel who experience exposures.

6.1.7.1.4 General compounding practices that are different than or in addition to compounding of non-hazardous drugs (if applicable)

6.1.7.1.5 Negative pressure techniques to be used inside a BSC

6.1.7.1.6 Proper use of closed system vial-transfer devices (CSTDs) (if applicable)

6.1.7.2 HD training will be successfully completed prior to allowing employees to handle or compound HDs.

6.1.7.3 All pharmacy staff must successfully complete HD training annually.

6.1.8 HD Risk Acknowledgement

6.1.8.1 All employees who may handle or compound HDs must read and sign the HD Risk Acknowledgement Form (AHCT-FORM-0030) since adverse effects of HD exposure are not limited to those of child-bearing age.

6.1.9 Alternate Duty

6.1.9.1 If requested by a physician in writing, it is recommended that workers be given the option of alternate duty under the following circumstances:

6.1.9.1.1 Females who are pregnant.

6.1.9.1.2 Females who are breastfeeding.

6.1.9.1.3 Males or Females actively trying to conceive a child.

6.1.9.2 In the case of an HD spill, notify a pharmacist and a member of the SRT immediately. Refer to AHCT-WI-0123 for Spill Management.

6.1.9.3 Department Supervisor will document on FORM-0098 if needed. Once completed, the Department Supervisor will submit to the Environmental Health and Safety Specialist.

6.2 Engineering Controls (equipment or facilities that are designed to contain hazardous substances thereby reducing the risk of employee exposure)

6.2.1 Sterile and Non-Sterile HD compounding will be performed in SECs that are externally vented and negative pressure between 0.01-0.03 inches of water column.

6.2.1.1 SECs used for sterile compounding must be in an ISO 7 buffer room with 30 ACPH adjacent to a positive pressure (minimum of 0.02" w.c.) ISO 7 anteroom.

6.2.1.2 SECs used for non-sterile compounding must have 12 ACPH.

6.2.2 Class II BSCs used for sterile HD compounding, must be externally vented.

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Procedure #: **AHCT-SOP-0040**	Revision: 9 Effective Date: 14 Oct 2024

6.2.3 Containment hoods and BSCs (Class I or II) used for non-sterile HD compounding must have redundant HEPA filters or be externally vented.

6.2.4 Areas where HDs are handled must have a sink with an eye wash station. An alternative which is functionally equivalent and cost effective includes:

6.2.4.1 Irrigation bag of sterile water, USP or 0.9% sodium chloride with attached tubing.

6.3 Work Practice Controls

6.3.1 Work practice controls are the specific ways of handling hazardous drugs that reduce employee exposure.

6.3.2 Work practice controls include but are not limited to:

6.3.2.1 Use of specific PPE to provide a barrier between the worker and HD.

6.3.2.2 All personnel handling HD shall be instructed on proper garb procedures before compounding of HD is performed.

6.3.2.2.1 Gloves must be powder free and changed immediately after compounding a hazardous drug.

6.3.2.2.1.1 Gloves for compounding must be ASTM rated as chemotherapy gloves.

6.3.2.2.1.2 Double gloves must be worn when compounding with any drug listed on FORM-0071.

6.3.2.2.2 Safety glasses, goggles, or other eyewear (if applicable – refer to NIOSH 2016 Table 5) must be used to protect eyes when splashing of HD solutions or vapors is likely to be encountered.

6.3.2.2.3 Back closing gown with long sleeves and elastic wristbands.

6.3.2.2.4 Head bonnet

6.3.2.2.5 Beard cover (if necessary)

6.3.2.2.6 Shoe covers (double shoe covers for any drug listed on FORM-0071).

6.3.2.2.7 Face mask or NIOSH approved respirator (if applicable per SDS)

6.3.2.2.7.1 OSHA certified fit tested respirators (N-95 or N-100) are used in the event that exposure to vapors is likely such as during spill cleanup.

6.3.2.2.7.2 See AHCT-WI-0028 for Respirator Fitting Instructions

6.3.2.3 No PPE is worn outside of the designated compounding area and is discarded appropriately.

6.3.2.4 Utensils, tools, beakers, etc. used for HD compounding are clearly marked so they are only used for HDs.

6.3.2.5 For sterile HDs - Use of negative pressure and other compounding techniques specifically designed to maintain sterility (protect the product from the environment) but additionally protect the worker from the HD product.

Section Name: **Training**	Procedure Name: **Hazardous Drug Employee Training and Safety Program**
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6.3.2.6 Syringes, vials, bags, and pumps should be wiped clean of any HD contamination.

6.3.3 All HDs shall be weighed in a containment hood or BSC.

6.3.4 Containment hoods and BSCs used for hazardous compounding must first be decontaminated prior to being cleaned.

6.3.5 Decontamination must be performed as a part of daily cleaning and in the event of a spill.

Date	Name	Action
10/21/2013; 6/20/16	K. Yost	Created from P-513
4/25/17	K. Yost	Added 6.3.2.2.1.2; 6.3.2.2.5; 6.3.2.3; added detail to 6.3.2.2.6 per CA requirements
11/14/2018	K. Yost	Updated NIOSH to most recent list; added 6.1.3.2; added 6.1.11.3-6.1.11.7; removed attachment A; updated signature lines
4/22/2020; 5/7/2020	K. Yost	Updated 5.5 and 5.6 to "Current" list; added "or designee" to 6.1.3.2; added "notify a pharmacist and refer to SDS" to 6.1.10; added 6.1.10.1; updated 6.1.10.2 with current Works Comp reference; updated 6.3.2.2.1.2 and 6.3.2.2.6 from "Table 1" to "list"; removed signature lines; added 5.3 and 5.9
12/29/2020	K. Yost	Removed GenPharm powerpoint training from Section 5; added forms to 5.6,5.9, and 6.1.1; added Critical Point Training to 6.1.7.1
1/18/2022	K. Yost	Updated 5.2
2/1/2023	K. Yost	Added Teams location to 6.1.3.1; updated 6.1.9.3 to Supervisor; changed 6.2.3 to "required"; added 6.3.2.4
5/18/2023	K. Yost	Added 6.1.2.1 from USP 800
10/5/2023	K. Yost	Removed CACI throughout; added 5.11; updated 6.1.3.1; updated 6.1.9.2 and 6.1.9.3; added 6.2.1-6.2.3; changed NIOSH list to FORM-0071 in section 6.3.2; added back closing gown to 6.3.2.2.3
9/27/2024	K. Yost	Updated header to "procedure"; 6.1.9.3 changed "HR" to "Environmental Health and Safety Specialist"; 6.3.2.6 removed "IV bottles"

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SOP-0040 Hazardous Drug Employee Training and Safety Program

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	30 Sep 2024, 10:39:20 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	30 Sep 2024, 01:25:53 PM	Approved

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Section Name: **Inventory Storage and Handling**	Procedure Name: **Prescription Delivery Procedure**
Procedure #: **AHCT-SOP-0043**	Revision: 8 Effective Date: 24 Dec 2024

1.0 Purpose

1.1 To outline the requirements and procedures necessary to ensure the storage and integrity of prescriptions dispensed from AnazaoHealth.

2.0 Scope

2.1 This applies to AnazaoHealth shipping department in Tampa.

3.0 Responsibilities

3.1 PIC, or designee, is responsible for ensuring that all AnazaoHealth shipping department employees receive training and that procedures are adhered to.

4.0 Definitions

4.1 AHPS – AnazaoHealth Pharmacy System

4.2 USP – United States Pharmacopeia

4.3 PIC – Pharmacist in Charge

5.0 Reference Documents:

5.1 AHCT-WI-0124 Pharmacy Shipping Instructions

5.2 AHCT-WI-0126 Shipping Information Verification

5.3 Package Engineering Studies and/or validations (located on SharePoint>Forms>Shipping)

6.0 Equipment and Materials:

6.1 Thermal coolers

6.2 Boxes, totes, or extreme cooler bags

6.3 Freezer gel packs

7.0 Procedure:

7.1 Prescription deliveries may be performed by FEDEX or another common carrier or a contracted courier service.

7.2 All prescriptions delivered from AnazaoHealth will be placed in an approved packaging capable of maintaining temperature requirements necessary to ensure prescription integrity if needed. Data logs have been used during shipping engineering studies to validate temperatures during shipments.

7.3 All prescriptions are packaged as required by USP and/or applicable regulatory requirements.

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7.4 Upon completing the final prescription inspection check, all prescriptions will be moved into the appropriate designated area.

7.5 When required, freezer gel packs must be placed inside the approved packaging containing the prescription to maintain proper shipping temperatures.

7.6 Prior to leaving AnazaoHealth, all necessary paperwork must be completed and either given to the delivery service or enclosed in the approved packaging.

7.6.1 Each package must contain instructions on how to report concerns with delivery and storage of medicinal drugs.

7.7 A scan through AHPS must be completed prior to releasing any packages containing all prescriptions prepared.

7.8 AHPS will link a shipping tracking number to the prescription, which can be readily retrieved through electronic documentation by individual delivery services.

7.9 Any exceptions to this policy must be approved by the PIC or designee.

Date	Name	Action
9/10/2012	K. Yost	Updated format, header, added signature lines
12/17/2012	K. Yost	Added to section 4.2
12/2/2013	K. Yost	Updated Material Control Manager to Facilities Manager; updated signature lines
1/30/15	J. Hauser	USP797 requirement changes; Updated signature log; Added 4.2.1, 5.5; Updated 3.1, 4.2, 4.5, 6.2, 7.1, 7.2, 7.3, 7.5
3/24/15	N. Benson	Updated language in 3.1; Moved 4.2.1 to 5.6 and updated language; Updated language for 4.3 and 5.6; Removed 4.4.
1/26/2017	K. Yost	Updated format and signature lines; added section 4;
3/29/2018	K. Yost	Updated 5.5; replaced "CSP" with "prescription" throughout; updated signature lines
8/15/2019	K. Yost	Updated to PIC in 3.1 and 7.9; removed signature lines
11/19/19	D. Davis	Removed USP <797> from reference documents. Updated 7.6 to include statement regarding how to report issues with package or delivery.
12/15/20	K. Yost	Added "When Required" to 7.5
3/26/21	S. Patterson	Updated Name of document 5.1 "AHCT-WI-0124 Pharmacy Shipping Instructions". Removed "Nuclear Pharmacy Shipping Instructions" from documents, no longer applicable. Removed "refrigerant cooling blocks, wet ice blocks ore dry ice" from section 7.5 replaced with "freezer gel packs".
8/10/22	K. Yost	Annual review – no changes
12/11/23	K. Yost	Annual review – no changes
12/9/24	K. Yost	Updated header with Procedure

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personalizing medicine

Document Number: AHCT-SOP-0043

Document Title: Prescription Delivery Procedure

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Author: KIMBERLY.YOST	Previous Number: P-508
Owner: AHCT-Quality Approver	Change Number: AHCT-DCR-1173

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Signature Manifest

Document Number: AHCT-SOP-0043 **Revision:** 8
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SOP-0043 Prescription Delivery Procedure

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	10 Dec 2024, 07:40:41 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	10 Dec 2024, 09:50:44 AM	Approved

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Section Name: **Environmental Monitoring (EM)**	Procedure Name: **Environmental Monitoring Program for the Sterile Suite**
Procedure #: **AHCT-SOP-0093**	Revision: 1 Effective Date: 05 Sep 2024

1.0 Purpose

1.1 This program will describe the overall Environmental Monitoring Program for the Sterile suite at AnazaoHealth Corporation (AHC) Tampa facility.

1.2 To monitor and evaluate the viable bioburden of air and surfaces of the Sterile suite at AHC Tampa and to assess and define critical factors. These factors will demonstrate that engineering controls, sanitization practices, and production processes provide an environment that is consistently capable of maintaining acceptable microbial levels.

2.0 Scope

2.1 The controlled areas in the AHC Tampa Pharmacy Sterile suite include ISO 8 anteroom, ISO 7 hallway, ISO 7 non-Hazardous buffer rooms, ISO 7 Hazardous vestibule, ISO 7 Hazardous buffer rooms, ISO 5 vestibule, ISO 5 suite and PECs.

3.0 Responsibilities

3.1 The Quality Assurance Manager, or designee, is responsible for maintaining and reviewing this document for appropriateness and compliance with regulations and AnazaoHealth requirements.
3.2 The Microbiology Supervisor is responsible for enforcing this program.
3.3 The Microbiology Supervisor, or designee, will be responsible for training personnel on executing this program.
3.4 Microbiology Technician, or designee, is responsible for following this program.
3.5 Offsite laboratories are responsible for analyzing submitted queries and reporting the results to the Microbiology Supervisor, or designee.

4.0 Definitions

4.1 CFU- Colony forming units
4.2 HD- Hazardous Drug
4.3 EM- Environmental Monitoring
4.4 DCA- Direct Compounding Area
4.5 TSA- Trypticase Soy with lecithin and polysorbate 80 agar fill
4.6 SDA- Sabouraud Dextrose with lecithin and polysorbate 80 agar fill
4.7 SAS- Surface Air Sample
4.8 VP- Viable Particulate (collected with SAS)
4.9 SM- Surface monitoring
4.10 sIPA- Sterile Isopropyl Alcohol
4.11 OOS- Out of Specification
4.12 PEC- Primary engineering control (LAFWs, BSCs)
4.13 SEC- Secondary engineering control (buffer room)
4.14 Dynamic conditions- production and personnel present during sampling
4.15 Static conditions- production or personnel are not present during sampling

5.0 Reference Documents

5.1 USP Chapter <797>

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5.2 USP Chapter <1116>
5.3 AHCT-WI-0024 SAS 100 and SAS 360 Air Sampler
5.4 AHCT-SOP-0034 Sterile Gowning Procedure
5.5 AHCT-FORM-0047 Sterile Suite Sampling Diagrams
5.6 AHCT-FORM-0050 Sterile Suite Environmental Monitoring Logs
5.7 AHCT-FORM-0017 Facility and Personnel Environmental Monitoring Investigation Report
5.8 AHCT-WI-0129 Microbial Identification
5.9 AHCT-FORM-0101 End of Batch Surface Sampling
5.10 AHCT-FORM-0102 Microbiology Media Control Testing

6.0 Safety/Precautions

6.1 Read and understand any Material Safety Data Sheets for listed materials.
6.2 When cleaning the SAS Air Sampler, do not allow liquids to drip or spray into electrical components.

7.0 Program Outline

7.1 Risk Assessment
- 7.1.1 Description of compounding practices
  - 7.1.1.1 Dissolving non-sterile bulk drugs and powders to make solutions that will be sterile-filtered or terminally sterilized.
- 7.1.2 Description of Sample Site Selection
  - 7.1.2.1 An Environmental Monitoring Performance Qualification (EMPQ) was performed in the Sterile suite after facility construction was completed.
  - 7.1.2.2 EMPQ Risk Assessment was used to determine the sample site selection for the EMPQ sampling locations.

7.2 Materials/ Equipment
- 7.2.1 Calibrated SAS 360Duo from Bioscience International
- 7.2.2 Two stainless steel sampling heads
- 7.2.3 Two protective white sampler head caps
- 7.2.4 TSA and SDA media plates
  - 7.2.4.1 Sterile packaged/ Certificate of Sterility required from manufacturer
- 7.2.5 Sterile gloves and garb according to AHCT-SOP-0034
- 7.2.6 Sterile 70% sIPA, Peridox RTU, and sterile non-shedding wipes
- 7.2.7 AHCT-FORM-0047 Sterile Suite Sampling Diagrams.
- 7.2.8 AHCT-FORM-0050 Sterile Suite Environmental Monitoring Logs.

7.3 Sample Plan
- 7.3.1 Design of Sample Plan
  - 7.3.1.1 Sample sites are chosen based on workflow processes of PECs and SECs, personnel activity, data accumulated from the EMPQ, and overall potential risk to product.
  - 7.3.1.2 The Bi-Weekly Air and Weekly Surface Sample Plan will be completed during dynamic conditions and can be completed during static conditions per Microbiologist discretion.
  - 7.3.1.3 Daily Sampling will be performed each day sterile compounding occurs in AHC Sterile suite during dynamic conditions.
  - 7.3.1.4 The sample IDs from AHCT-FORM-0047 must be used for sampling.
- 7.3.2 Sampling Type
  - 7.3.2.1 (VP) Viable air sampling is conducted using a volumetric Surface Air System (SAS).
  - 7.3.2.2 (SM) Surface sampling is conducted using contact plates.
  - 7.3.2.3 Each sample site will be sampled using TSA and SDA media.
    - 7.3.2.3.1 **NOTE**: TSA only for GFT samples

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7.3.3 Frequency

7.3.3.1 Bi-Weekly Air Sample Plan

7.3.3.1.1 The Bi-Weekly Air Sample Plan will be completed every other week.

7.3.3.1.2 A minimum of two Bi-Weekly Air Samplings are to be conducted every month.

- *A Bi-Weekly Air Sampling may also be performed:*
- For investigational purposes in response to OOS results,
- After a shutdown for any length of time, including greater than 24 hours, depends on cleaning hold time study.
- After significant maintenance work has been done on the ventilation system or the Sterile suite.
- After a patient incident in which the compounded material is suspect,
- After unplanned incidents that could contribute to biocontamination,
- Per Microbiologist discretion.

7.3.3.1.3 Volumetric air sampling of ISO 7 and 8 locations will be performed during Bi-Weekly Air Sampling using the sample sites located in AHCT-FORM-0047 *Sterile Suite Sampling Diagrams.*

7.3.3.1.4 A GFT will be taken from two randomly selected compounding personnel, during in-process ISO 5 conditions. The personnel selected for GFT will be rotated to avoid consecutive sampling.

7.3.3.2 Weekly Surface Sample Plan

7.3.3.2.1 The Weekly Surface Sample Plan will be completed once each week.

7.3.3.2.2 A minimum of four Weekly Surface Samplings are to be conducted every month.

- *A Weekly Surface Sampling may also be performed:*
- For investigational purposes in response to OOS results,
- After a shutdown for any length of time, including greater than 24 hours, depends on cleaning hold time study.
- After significant maintenance work has been done on the ventilation system or the Sterile suite.
- After a patient incident in which the compounded material is suspect,
- After unplanned incidents that could contribute to biocontamination,
- Per Microbiologist discretion.

7.3.3.2.3 Viable surface sampling of the ISO 7 and 8 locations will be performed during the Weekly Surface Sampling using the sample sites located in AHCT-FORM-0047 Sterile Suite Sampling Diagrams.

7.3.3.3 Daily Sampling

7.3.3.3.1 Volumetric air sampling will be performed a minimum of once each day sterile compounding occurs for all ISO 5

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BSCs and LAFWs in the Sterile suite during dynamic conditions.

7.3.3.3.2 Surface sampling will be performed a minimum of once each day sterile compounding occurs for all ISO 5 BSCs, LAFWs and all ISO 7 tabletops (adjacent to the ISO 5 BSCs & LAFWs) in the Sterile suite during dynamic conditions.

7.3.3.3.3 **NOTE:** Out of service BSCs/LAFWs or equipment will be sampled per Microbiologist discretion.

7.3.3.3.4 Daily Sampling will be performed during the AM shift and the PM shift. The Daily viable air and surface samples will be collected using the sample sites located in AHCT-FORM-0047.

7.3.3.3.5 If a room in the Sterile suite is not used during the week, it will require a daily and weekly sampling to be completed before the end of the week.

7.3.3.4 Sample Frequency by Room

Room Name	Room #	Sample Frequency		
		Daily	Weekly	Bi-Weekly
Anteroom	153		x	x
Sterile 1	144	x	x	x
Sterile 2	149	x	x	x
Sterile 3	151	x	x	x
Inventory	145		x	x
Sterile HD 1	143	x	x	x
Sterile HD 2	150	x	x	x
HD Vestibule	142		x	x
Sterile ISO 5	148	x	x	x
ISO 5 Vestibule	180	x	x	x
Degown	152		x	x
HD Degown	140		x	x
Sterile Hallway-South	147		x	x
Sterile Hallway-North	141		x	x

7.3.3.5 End of Batch Surface Sampling

7.3.3.5.1 Surface Sampling (in the ISO 5 BSCs/LAFWs) will be performed in accordance with *Section 8.3*, at the end of each batch before cleaning has occurred.

7.3.3.5.2 **NOTE**: AHCT-FORM-0101 must be used to document the sampling.

7.3.3.6 Lyophilized Product Sample Plan

7.3.3.6.1 EM will be performed during each lyophilized product batching process.

7.3.3.6.2 The EM requirements for lyophilized batches are outlined in AHCT-WI-0098.

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7.3.4 Environmental Monitoring Sampling Logs
- 7.3.4.1 The "Bi-Weekly Air Sampling Log" and "Weekly Surface Sampling Log" located in AHCT-FORM-0050 will be used to document the Bi-Weekly Air and Weekly Surface Sampling performed in the Sterile suite.
- 7.3.4.2 The "Daily Air Sampling Log" and "Daily Surface Sampling Log" located in AHCT-FORM-0050 will be used to document daily sampling performed in the Sterile suite.
- 7.3.4.3 The "End of Batch Surface Sampling Log" located in AHCT-FORM-0101 will be used to document the End of Batch Surface Sampling.
- 7.3.4.4 If sampling cannot be performed for a scheduled EM event, the reason must be documented in the "Comments" section of the appropriate logs with the date and shift noted.
- 7.3.4.5 Exceeded alert or action levels must be noted on the EM log and reported to Microbiology Supervisor.
  - 7.3.4.5.1 If any re-samples are to be collected, it must be documented on the original sample log and the re-sample recorded on its own log.
- 7.3.4.6 All completed and signed sampling logs must be turned into the Microbiology Supervisor, or designee, for review.

7.3.5 Training
- 7.3.5.1 Training on this procedure will be conducted by Microbiology Supervisor, or designee, and will be documented on Simplifi797 ®.

7.3.6 Review
- 7.3.6.1 This program will be reviewed at a minimum on an annual basis for appropriateness and compliance with standards and regulations.

8.0 Sampling Procedures

8.1 General
- 8.1.1 Prior to an EM Sampling Event, review the Sampling Plan, print the appropriate EM Sampling Log from AHCT-FORM-0050, print the appropriate diagram from AHCT-FORM-0047 and gather the materials needed.
  - 8.1.1.1 The most updated revision of AHCT-FORM-0047 can be laminated and stored in the Sterile suite with the Micro supplies.
- 8.1.2 Examine media for integrity and contaminants (without opening the plates).
- 8.1.3 Label each media plate in accordance with *Section 9.0* before sampling is performed.
- 8.1.4 Record EM Sampling Event information and data in accordance with *Section 9.0* on the correct EM log from AHCT-FORM-0050 or AHCT-FORM-0101 (End of Batch Surface Sampling).
- 8.1.5 Gown according to AHCT-SOP-0034; sterile gloves are required.
- 8.1.6 Sanitize gloves with 70% sIPA before and after each air and surface sample and periodically.
  - 8.1.6.1 If the sampler feels they may have compromised the cleanliness of their gloves, a new pair of sterile gloves must be donned.

8.2 Viable Room Air Samples (VP)
- 8.2.1 The volume of air collected for the SAS 360Duo volumetric air sampler is **1000 liters** per sampling head in all ISO class 5, 7, and 8 areas.
- 8.2.2 For full instructions on how to operate the SAS 360Duo Air Sampler, refer to the operator's manual and AHCT-WI-0024.
- 8.2.3 Gather the stainless-steel sampler heads and white sampler heads caps.

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8.2.4 The stainless-steel sampler heads can be found on the supply cart in the buffer room and the protective white sampler caps are stored with the Micro supplies and do not leave the buffer room.
- 8.2.4.1 The stainless-steel sampler heads are depyrogenated in a dry heat oven and remain in their foil wrapping until use.
- 8.2.4.2 **NOTE:** If using non-depyrogenated SAS heads, disinfect the SAS heads with sterile Peridox RTU followed by 70% sIPA before use.

8.2.5 Using sterile, non-shedding wipes, sanitize the SAS sampler, sampler heads, and caps with 70% sIPA before use.
- 8.2.5.1 Sanitize the sampler heads and caps with 70% sIPA between each air sample collected.

8.2.6 The SAS sampler, sampler heads, and caps must rest on sterile, non-shedding wipes at all times.

8.2.7 Select the appropriate settings on the SAS air sampler:
- 8.2.7.1 "Left and Right" heads must be selected.
- 8.2.7.2 The SAS is already set to 1000L.
  - 8.2.7.2.1 Sampling volume is not to be adjusted without approval of the Microbiologist.
  - 8.2.7.2.2 Approved adjustments need a reason and a calculation adjustment documented on the EM log.

8.2.8 Place one TSA and one SDA media plate on the holders, one for each head. Aseptically remove the plate lid, and immediately place the sampling head with attached protective cap, one plate at a time.
- 8.2.8.1 Media plate lids must be placed open side down on the sterile wipe.
- 8.2.8.2 White caps are required for placement into and removal from ISO 5 areas.

8.2.9 Move the SAS sampler to the designated location.
- 8.2.9.1 Place the sampler at the same height as the product or 12" above equipment.
- 8.2.9.2 In an ISO 5 LAFW, the sampler will be positioned in an upright position, in line with the workspace, just outside of the DCA, not directly in the DCA.
  - 8.2.9.2.1 The sampler should not be more than 6" from the back of the LAFW.
- 8.2.9.3 In an ISO 5 BSC, the sampler will be in an upright position, just outside of the DCA, and not near openings/critical sites.
  - 8.2.9.3.1 The vertical air flow of the BSC could cause contamination if the sampler is directly above or near these sites.
  - 8.2.9.3.2 The BSC sash should remain at least halfway closed during sampling.
- 8.2.9.4 For ISO 5 samples, the SAS sampler and caps must rest on a non-shedding sterile wipe obtained from the Hood where sampling will occur.
  - 8.2.9.4.1 The protective caps must be placed open side down on the sterile wipe.
- 8.2.9.5 Once the cycle is complete (approximately 5 minutes) replace the protective caps and remove air sampler from ISO 5 area.

8.2.10 Aseptically remove the sampler heads, replace the media plate lids, and remove the plates from the SAS sampler one at a time.

8.2.11 Aseptic processes must be followed throughout air sampler manipulations and sampling.

8.3 Viable Surface Samples (SM)

8.3.1 Surface samples will be taken from ISO class 5, 7, and 8 areas.

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8.3.1.1 Samples will be taken of areas of perceived high usage or personnel contact.

8.3.2 Surface sampling in the ISO 5 space is completed towards the end of compounding, i.e., during the "check" stage or before the removal of a completed compound.

8.3.2.1 The DCA must be sampled, near where most of the manipulations occur.

8.3.2.2 Aseptic processes must be followed to minimize contamination to the DCA; refrain from touching anything other than the plates and wipes.

8.3.3 Carefully remove the lid from the plate with one hand. With the other hand, hold the base (agar portion of the plate) with thumb and middle finger. Use index finger to gently press the plate on the test surface. Make sure the entire agar surface touches the test surface. Do not move the plate laterally while sampling as it will spread contaminates making enumeration difficult. Immediately replace the lid on the plate.

8.3.3.1 In the ISO 5 area, **at no point are the exterior of the plates or the sampling personnel's gloves to contact the deck of the PEC.** Plates should be held during this process or placed on a sterile, non-shedding wipe (obtained from the Hood being sampled) outside of the DCA.

8.3.4 Saturate a wipe with 70% sIPA, wiping should be conducted in a unidirectional motion (cleanest to dirtiest) to remove any residual media.

8.3.4.1 **Saturated wipes are to be used in the ISO 5 PECs to avoid damage to the HEPA filters and avoid contamination or disruption of compounding.**

9.0 Documentation

9.1 EM Sampling Logs

9.1.1 EM log documentation must include:

9.1.1.1 Correct list of sample sites; "N/A" sites not sampled,

9.1.1.2 Dynamic/ Static conditions,

9.1.1.3 Shift AM/ PM

9.1.1.4 Media type, lot number, expiration date, and manufacturer,

9.1.1.5 Number of personnel in the room including the sampler,

9.1.1.6 SAS serial number, calibration due date, and sample volume,

9.1.1.7 Any deviations to the sample plan notated in the comments,

9.1.1.8 Reason for sampling- routine, resample, etc. if applicable.

9.1.2 Data from the start of an EM event through the incubation results will be recorded on the appropriate forms outlined in *Section 7.3.4.*

9.1.2.1 All results will be logged on the corresponding Excel Spreadsheets located in Microsoft Teams under *Microbiology -> General -> Micro Dept Environmental Monitoring* for trending purposes.

9.1.3 Microbiology Supervisor, or designee, must be notified of alert and action levels.

9.2 Sample Documentation

9.2.1 Media plates will be labeled for sampling as follows:

9.2.1.1 Sample ID,

9.2.1.2 Date of collection (and time designation, if appropriate),

9.2.1.3 Initials of sampling personnel

9.2.1.4 Volume, if appropriate

10.0 Incubation/Analysis

10.1 Incubate the TSA plates (lid side down) at 30°C to 35°C for no less than 48 hours. Incubate the SDA plates inverted (lid side up) at 20°C to 25°C for no less than five days.

10.1.1 **NOTE: Use FORM-0022 to collect and incubate GFT samples.**

10.2 Place sample plates in sterile "Whirl-pak" bag for incubation. Parafilm can be used in place of sterile bags.

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10.3 See SOP AHCT-WI-0129 Microbial Identification for instructions on how to analyze and process EM samples.

11.0 Expression, Interpretation, and Reporting of Results

11.1 Data Expression

11.1.1 All recovered colonies will be counted as CFU and reported on each media type.

11.1.2 Viable air samples will be expressed as cfu/m^3.

11.1.3 Surface samples will be expressed as CFU per plate.

12.0 Acceptance Criteria

12.1 Alert and action levels are established according to USP <797>.

12.1.1 CFU alert and action levels are as follows.

ISO classification	Air Sample Alert Level (cfu/m^3)	Air Sample Action Level (cfu/m^3)	Surface Sample Alert Level (CFU per plate)	Surface Sample Action Level (CFU per plate)
ISO 8	>50	>100	>20	>50
ISO 7	>5	>10	>3	>5
ISO 5	>0	>1	>0	>3

12.1.2 If a failure is identified on a TSA plate, the corresponding area will be cleaned with a sporicidal solution, documented in Simplifi 797® (when applicable) and on the appropriate sampling log. The area will be resampled within 24 hours (excluding weekends and holidays) of reporting the failing result.

12.1.3 If a failure is identified for an SDA plate, the corresponding area will be cleaned with a sporicidal solution, documented in Simplifi 797® (when applicable) and on the appropriate sampling log. The area will be resampled within 24 hours (excluding weekends and holidays) of reporting the failing result.

12.2 The Microbiology Supervisor, or designee, will be notified in the event of OOS results.

12.3 Action levels exceeded and the identification of any fungus, Gram negative rods, or Coagulase positive organisms will be evaluated for risk severity on the AHCT-FORM-0017 *Facility and Personnel Environmental Monitoring Investigation Report.*

12.4 Appropriate statistical tools will be used to analyze the data on a quarterly and annual basis to establish concern levels and determine the state of control of the Sterile suite.

Date	Name	Action
6/14/2024	T. Zabinski	New SOP
8/14/2024	A. Oliver	Added macros

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Author: TANIA.ZABINSKI	Previous Number:
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Environmental Monitoring Program for the Sterile Suite

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	30 Aug 2024, 11:23:34 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	30 Aug 2024, 02:55:18 PM	Approved

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Section Name: **Compounding**	Procedure Name: **Cleaning and Disinfection of the Sterile Suite**
Procedure #: **AHCT-SOP-0095**	Revision: 2 Effective Date: 14 Nov 2024

1.0 Purpose

1.1 To describe, standardize, and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the unclassified General Pharmacy Area are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations. Human and environmental contact are a major source of microbial contamination of CSPs, therefore scrupulous attention to cleaning and disinfecting of the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

2.0 Scope

2.1 This applies to pharmacists, technicians, and any personnel involved in cleaning the compounding area at AnazaoHealth Tampa.

3.0 Responsibilities

3.1 Pharmacy Manager, or designee, is responsible for ensuring that all affected employees receive training and that procedures are adhered to.

4.0 Definitions

4.1 CSP – Compounded Sterile Preparation

4.2 DCA- Designated Compounding Area

4.3 LAFW – Laminar Airflow Workbench

4.4 BSC – Biological Safety Cabinet

4.5 GFT – Gloved Fingertip and Thumb Sampling

4.6 PEC – Primary Engineering Control

4.7 SEC – Secondary Engineering Control

5.0 Reference Documents

5.1 AHCT-SOP-0094 Sterile Gowning Procedure

5.2 AHCT-SOP-0036 Orientation, Training, and Competency Evaluation of Pharmacy Personnel

5.3 AHCT-FORM-0027 Gowning Competency and GFT Log

5.4 AHCT-SOP-0037 Conduct of Personnel and Aseptic Techniques

5.5 Critical Point Training

5.6 Simplifi797®

5.7 AHCT-FORM-0029 Cleaning and Disinfecting Competency

5.8 AHCT-WI-0026 Glove Fingertip Sampling

5.9 AHCT-FORM-0031 Hazardous Drug Spill Report Form

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Section Name: **Compounding**	Procedure Name: **Cleaning and Disinfection of the Sterile Suite**
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6.0 Materials and Equipment

6.1 Plastic/stainless steel mop handles suitable for mop heads used

6.2 Disposable micro-fiber mop heads

6.3 Low particle shed wipes

6.4 Sterile low particle shed wipes

6.5 Appropriate sterile disinfectant agents:

6.5.1 sterile LpH – (germicidal cleaner, disinfectant) minimum 10-minute dwell time

6.5.2 sterile Vesphene – (germicidal cleaner, disinfectant) minimum 10-minute dwell time

6.5.3 Spor Klenz – (cleaner, disinfectant, sporicidal) minimum 10-minute dwell time

6.5.4 Sterile Peridox RTU – (cleaner, disinfectant, sporicidal, deactivation and decontaminant agent) minimum 3-minute dwell time

6.6 70% Sterile IPA (sIPA)

6.7 Decon-clean

6.8 Sterile bucket liners

6.9 Tacky mats

6.10 Sterile Water (sterile water for injection or irrigation)

7.0 Policy

7.1 The Microbiologist will designate appropriate cleaning agents based upon careful consideration of compatibility, effectiveness, and appropriateness of cleaning and compounding residues and surface materials.

7.1.1 Any new cleaning agents will be tested for disinfection efficacy prior to being used in the clean room.

7.2 There is no scientific basis at the time of this policy writing to suggest that alternation of cleaning agents is necessary. The possibility of producing germicidal resistant microorganisms does not apply to cleaning of controlled pharmacy environments.

7.3 All personnel who perform cleaning and disinfecting functions must successfully complete the following:

7.3.1 Critical Point training – sections to include:

7.3.1.1 Personnel, Hand Hygiene, Garbing and GFT

7.3.1.2 Overview of Cleaning and Disinfection of Pharmacy Controlled Environments

7.3.1.3 Cleaning and Disinfection of PECs

7.3.1.4 Cleaning and Disinfection of SECs and Segregated Compounding Areas

7.3.1.5 Aseptic Technique and Conduct of Controlled Environments

7.3.2 AHCT-WI-0026 Gloved Fingertip Sampling

7.3.3 AHCT-FORM-0027 Gowning Competency and GFT Log

7.3.4 AHCT-FORM-0029 Cleaning and Disinfecting Competency

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7.4 In general, cleaning must occur from the cleanest areas to the dirtiest areas. The lowest ISO 5 classified areas, including PECs, must be cleaned before the ISO 7 classified buffer areas, followed by the ISO Class 8 anteroom (clean side)/de-gowning rooms, and lastly the ISO 8 classified anteroom (dirty side).

7.4.1 Perform necessary restocking or other in room activities prior to cleaning and floor cleaning so that buffer area/cleanroom may be exited and allowed to dry and remain at rest until the next shift.

7.4.2 **NOTE:** Custodial/housekeeping personnel may NOT clean any ISO classified areas.

7.5 Any compounding equipment (i.e., automated compounders, devices, or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW and BSC itself.

7.5.1 If any sterile compounding equipment is removed from the ISO Class 5 area or the ISO 7 buffer area/cleanroom, it must be cleaned and disinfected according to AHCT-SOP-0037 prior to being placed back into service within that environment.

7.6 An "easily cleanable work surface" means easily cleanable horizontal surfaces including, but not limited to, tabletops, work surfaces, cart and table shelves, tops of microwaves, tops of trash cans, and bottom cross bars of tables.

7.7 Though the General Pharmacy Area is not an ISO classified environment it must be kept clean and orderly and is included in *Section 13.0.*

7.8 Ideally, cleaning of the PECs, buffer area, and ante-areas should occur at the end of compounding day to prevent any component residue from sitting overnight and promoting bacterial growth.

7.8.1 If cleaning occurs at the start of the compounding day, adequate time must be given to allow all cleaned surfaces to dry prior to starting any compounding activity.

7.8.2 If any compounding occurs during after-hours conditions (on-call situation), additional cleaning must occur after compounding and the tasks initiated and documented in Simplifi797®.

7.9 Cleaning and disinfection of the controlled environments will NOT be performed while compounding is taking place.

7.10 The gown and gloves worn during any cleaning activity must be discarded and replaced by a new sterile gown and sterile gloves prior to any compounding preparation.

7.11 The gloves worn during cleaning activities in any ISO 7 or ISO 8 areas must be discarded and replaced by new sterile gloves prior to cleaning any ISO 5 area.

7.12 Cleaning equipment and supplies:

7.12.1 Shall be stored in a designated area to ensure segregation from compounding supplies.

7.12.1.1 All buckets or sprayers used must be stored in the Sterile suite.

7.12.2 Materials used (wipers, sponges, mops, etc.) must be non-shedding and preferably composed of synthetic microfibers.

7.12.2.1 No high particle shedding materials may enter the ISO classified areas during cleaning. This includes corrugated cardboard or other non-compounding-related items.

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7.12.3 Sterile wipes must be used to clean inside any ISO 5 Classified area, including PECs.

7.12.4 Materials used must be dedicated to a particular area (buffer area/cleanroom, ante-area/room, segregated compounding area, etc.) and will not be moved from these areas except for disposal.

7.12.5 Ideally all cleaning tools are to be discarded after one use.

7.12.6 Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders which must be cleaned and disinfected before and after use in a PEC.

7.12.7 Floor mops may be used in the ISO 5 room, followed by the ISO 7 buffer area/cleanroom, then the ISO 8 anteroom (clean side)/de-gowning, and lastly in the ISO 8 anteroom (dirty side) as long as they are used in that order.

7.12.7.1 Sterile bucket liners must be used to ensure the disinfectants remain sterile.

7.12.7.1.1 A sterile liner must be placed inside the portion of the bucket where the sterile disinfectant will be used.

7.12.8 If using a sterile-lined mop bucket to perform cleaning, allow mop heads to soak in their solution for approximately 5 minutes prior to the start of cleaning.

7.12.9 A new disposable mop head will be used each day in the ISO 5/ISO 7/ISO 8 areas.

7.12.10 The same bucket may be used for the Walls/Ceiling cleaning and floor cleaning as long as the sterile bucket liner used for Walls/Ceiling is discarded and is replaced with a new sterile bucket liner for the floor cleaning.

7.12.11 For any reusable cleaning equipment:

7.12.11.1 Used mop heads will be removed from the pole immediately after use.

7.12.11.2 Buckets must be inverted and allowed to dry. Make sure the inverted buckets are propped up on one side to allow air to circulate.

7.12.11.3 Manufacturer's instructions for the equipment must be followed to ensure that the effectiveness of the device is maintained, and that repeated use does not add bioburden to the areas cleaned.

7.13 Prior to the start of cleaning:

7.13.1 Staff will gather the supplies needed.

7.13.2 Inspect for cleaning product expiration dates.

7.13.2.1 Agents will be labeled with initials, date of opening, and expiration date.

7.13.2.2 Once opened, sterile cleaning agents can be used for up to 10 days before discarding if used only in the controlled environment.

7.13.2.3 Note: Some agents have a Julian code printed by the manufacturer on the bottle which indicates the day the product was manufactured. Refer to the manufacturer's information for the recommended expiration date in relation to the Julian code.

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7.13.3 Some agents must be diluted. Follow manufacturer's recommendations regarding appropriate dilutions. Proper dilutions are stated within each cleaning task in Simplifi797®.

7.13.3.1 Appropriate amounts of the designated agents are measured using a graduated cylinder.

7.13.3.2 Sterile water (sterile water for injection or irrigation) must be used to dilute cleaning/disinfectant solutions according to manufacturers' directions.

7.13.4 Insert the sterile liner in the buckets, fill the B-7 bucket or stainless-steel bucket or sprayer bottle (if bucket-less system is used) with the appropriate amount of water then add the correct amount of sterile agent to the water to reduce the likelihood of splashing.

7.13.5 Document the preparation of the cleaning solution in Simplifi797® immediately after preparing the solution.

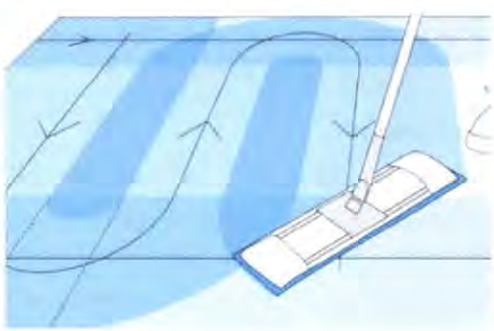
7.14 General considerations when cleaning floors:

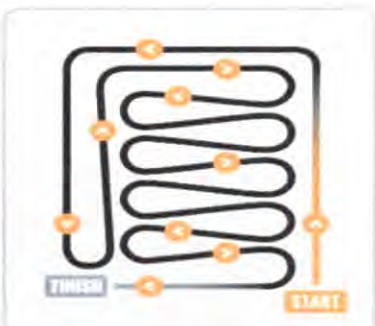
7.14.1 Clean floors after the ISO Class 5 areas and ISO 7 tabletops and other easily cleanable work surfaces have been cleaned and disinfected.

7.14.2 Begin at the location farthest from the buffer area/cleanroom entrance working toward the exit to avoid walking over cleaned areas.

7.14.2.1 If an item needs to be removed from an area already mopped, the employee must wait until the floor dries or re-mop the area after changing their shoe covers.

7.14.3 Thoroughly wet all surfaces completely and allow for the appropriate dwell time for the disinfecting solution. Using an "S" pattern to clean or apply solution, move side to side using overlapping strokes. Mopping in one direction creates an effective cleaning technique. Follow the pattern as indicated below, saturate the mop and repeat the pattern every 25 sq/ft (or 5 ft x 5 ft) section





7.14.4 Move any roll-able carts, shelving, and chairs as cleaning is completed.

7.14.4.1 **NOTE:** At no time is an ISO 5 LAFW or BSC to be moved. Prior to certification, they are placed away from the walls to allow cleaning to be done around the hood. If at any time they are moved, it will require recertification of the LAFW or BSC.

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7.15 Safety Considerations:

7.15.1 Safety goggles must be worn during cleaning of ceiling and walls when there is an increased likelihood of splashing or dripping of solution.

7.15.2 Safety Data Sheets must be readily available for reference in the pharmacy for all disinfectants used in the cleaning and disinfecting process.

7.15.3 **AHCT-FORM-0031 *Hazardous Drug Spill Report Form* is to be completed if a spill occurs with a hazardous drug.**

8.0 Cleaning LAFW / BSCs:

8.1 Gown and glove, in accordance with AHCT-SOP-0094 *Sterile Gowning Procedure.*

8.2 If the LAFW / BSC has been turned off, restart and allow to run a minimum of 30 minutes prior to cleaning. Ideally, PECs should never be turned off.

8.3 Inspect the inside of the hood/bench for any spills or puddles of crystallized compounding components. Clean the spills with sterile water prior to proceeding with the cleaning procedure.

8.4 At the start of each new workday, the LAFWs / BSCs must be wiped down with a sterile non-shedding wipe saturated with 70% sIPA as part of the *Morning Sanitization.*

8.4.1 **NOTE: Do not splash or spray the HEPA filter with solution. Carefully clean the HEPA grills.**

8.5 Begin cleaning within the LAFW / BSC environment by moving outward, working from inner to outer surface.

8.5.1 **NOTE:** The wipe should be used in a side to side, back to front motion to allow cleaning from the cleanest to "dirtiest" area. **DO NOT** wipe in a large circular motion across the work surface, as it is likely contaminants and particulate matter will be introduced into the rear portion of the hood as they are captured, carried, and deposited from the front edge of the PEC.

8.5.2 Place used wipers onto sterile wipe on hood deck, or discard while cleaning. Remove all used wipers after cleaning of the BSC/LAFW has been completed.

8.6 Additionally, ISO Class 5 PECs will be disinfected with 70% sIPA:

8.6.1 After cleaning to remove any residue,

8.6.2 Immediately before initiating compounding,

8.6.3 And to the horizontal work surface of a PEC at least every 30 minutes, or if compounding takes >30 minutes, disinfect immediately after compounding.

8.7 Any use of 70% sIPA is to remain in contact with surfaces for a minimum of 10 seconds.

8.8 BSCs used for hazardous compounding must first be decontaminated (using Peridox RTU, sodium hypochlorite, etc.) prior to cleaning.

8.9 Daily cleaning activities are documented in Simplifi797®.

9.0 Daily Cleaning and Disinfection (ISO 5, ISO 7 and ISO 8)

9.1 Each compounding day, all ISO 5, ISO 7, and ISO 8 areas will be cleaned and disinfected using the following agents:

9.1.1 Sporicidal disinfectant Peridox RTU

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9.1.2 Sterile disinfectants, LpH and Vesphene, on a rotating schedule.

9.1.2.1 Vesphene, a phenolic alkaline formulation, will be used daily during the EVEN months.

9.1.2.2 LpH, a phenolic acidic formulation, will be used daily during the ODD months.

9.1.2.3 The exact cleaning agent used is to be documented in Simplifi797®.

9.1.3 Sterile 70% IPA

9.2 Inside surfaces of all ISO 5 Class PECs will be cleaned with sterile Peridox RTU followed by 70% sIPA after the 3-minute dwell time.

9.3 Surfaces of tables will be cleaned and disinfected with Peridox RTU followed by 70% sIPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time.

9.4 All easily accessible horizontal ISO 7 and ISO 8 surfaces will be cleaned with either sterile Vesphene or sterile LpH followed by 70% sIPA after the 10-minute dwell time.

9.4.1 Powder hoods will be cleaned with sterile LpH or sterile Vesphene.

9.4.2 Anteroom: bench, sink, and dispenser will be cleaned with Peridox RTU followed by 70% sIPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time.

9.4.3 Degowning rooms: bench, sink, and dispenser will be cleaned with Peridox RTU followed by 70% sIPA after the 3-minute dwell time of Sporklenz followed by 70% sIPA after the 10-minute dwell time.

9.5 Floors will be mopped with either sterile LpH or sterile Vesphene.

9.6 Cleaning is performed in this order:

9.6.1 Inside surfaces of ISO Class 5 PECs

9.6.2 Tabletops and easily cleanable horizontal surfaces in the ISO 7 buffer area/clean room and pass-thrus.

9.6.3 Floors in the ISO 7 buffer area/cleanroom from farthest point away from the door progressing toward the door to the ISO 8 ante-area while moving easily moveable carts and shelving.

9.6.4 Tabletops, sink, and easily cleanable work surfaces in the ISO 8 ante-area as long as those areas are on the "clean side" of the line of demarcation.

9.6.5 Easily cleanable horizontal surfaces in the ante-area/room beyond the line of demarcation ("dirty side").

9.6.6 Floors of the ante-area/room.

9.6.7 Perform any required daily activities related to cleaning the pharmacy's general preparation area.

9.7 Sterile ISO 5 Room

9.7.1 Opening and closing cleaning is not necessary if no compounding or media fill activities will be occurring that day.

9.7.2 If the room was not used during the week, the weekly cleaning and disinfection must still occur *per Section 10.0.*

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9.7.3 For the Sterile ISO 5 room: Freeze dryer door and chamber with shelves cleaned with sterile LpH or sterile Vesphene with a dwell time of 10 minutes, followed by 70% sIPA.

9.8 Document all cleaning and agents used in Simplifi797®.

10.0 Weekly Cleaning and Disinfection (ISO 5, ISO 7 and ISO 8)

10.1 All easily accessible horizontal ISO 7 and ISO 8 surfaces will be cleaned with sporicidal disinfectant Peridox RTU followed by 70% sIPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time.

10.2 For the Sterile ISO 5 room all easily accessible horizontal ISO 5 surfaces will be cleaned with sporicidal disinfectant Peridox RTU followed by 70% sIPA after the 3-minute dwell time.

10.3 Floors will be mopped with sporicidal disinfectant Peridox RTU or Spor Klenz.

11.0 Monthly Sporicidal Cleaning and Disinfection (ISO 5, ISO 7, and ISO 8)

11.1 The time between performing Monthly Sporicidal Cleanings should not exceed 35 days.

11.2 All ISO 5, ISO 7, and ISO 8 areas will be cleaned with a sporicidal disinfectant followed by 70% sIPA:

11.2.1 The buffer area/cleanroom is cleaned before the ante-area/room.

The inside and outside of all ISO 5 PECs will be cleaned with sterile Peridox RTU followed by 70% sIPA after the 3-minute dwell time.

11.2.2 All surface areas of equipment will be cleaned with Peridox RTU followed by 70% sIPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time. These include but are not limited to work surfaces, tables, shelves, carts, microwaves, tops of trash cans, chairs, bottom cross bars of tables, table legs, etc.

11.2.3 All storage shelving and contents of bins must be removed and cleaned with Peridox RTU or SporKlenz, **inside** and **outside** of all bins cleaned with Peridox RTU, allowed to dry, followed by 70% sIPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time and then items replaced.

11.2.4 Walls, ceilings, and floors will be cleaned with a sporicidal disinfectant (Peridox RTU or Spor Klenz).

11.2.4.1 In this case, it may be appropriate to clean the inside of the ISO 5 areas immediately after the ceiling clean in case any dripping has occurred.

11.2.4.2 Prior to cleaning the ISO 5 areas, personnel must repeat the sterile gowning procedure, if they had previously cleaned in the ISO 7/ISO 8 areas.

11.3 Document the cleaning and cleaning agents used in Simplifi797®.

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12.0 Cleaning of Pass-thrus

12.1 All pass-thrus will be cleaned with sporicidal Peridox RTU followed by 70% IPA after the 3-minute dwell time or SporKlenz followed by 70% sIPA after the 10-minute dwell time to remove residue.

12.2 Evenly saturate wiper with disinfecting solution, can place wipers in resealable bag and add solution. Wipe in unidirectional, parallel, overlapping strokes for even coverage. Wipe from cleanest to dirtiest, back to front and work from top to bottom. Use a new saturated wipe every 10 wipe lengths. When wiping, place equal pressure across the edge of your hand, holding the fingers together and pull across the surface to be cleaned.

Pass-thru cleaning order:

1	Pass-thru frame	5	Hinges and closure latches
2	Exterior of box walls	6	Door/Window frame interior
3	Door/Window frame exterior	7	Door/Window interior
4	Door/Window exterior	8	Box interior, top to bottom

12.3 The Sterile Suite Pass-thrus will be cleaned twice daily from the cleanroom side: during the opening of the cleanrooms and at the end-of-day during cleanroom closing.

12.4 All pass-thru cleanings and sporicidal used will be documented in Simplifi797®.

13.0 Routine Cleaning of the General Pharmacy Preparation Area

13.1 Though not part of the controlled environments, cleanliness and order is required in the General Pharmacy to include the outside of the anteroom and degowning room doors and floor area.

13.2 The CNC Hallway floor will be mopped monthly with a sporicidal disinfectant (Peridox RTU or SporKlenz).

13.3 The General Pharmacy area must be cleaned at least monthly.

13.4 Document the cleaning in Simplifi797®.

13.5 Tacky Mats:

13.5.1 Shall be placed at the entrance to controlled areas within the General Pharmacy Area to remove debris from personnel and equipment as they enter these areas.

13.5.2 The Pharmacy Manager or designee will determine the location of the tacky mats depending on workflow and room configuration.

13.5.3 Reusable Washable Tacky Mats will be used at the Sterile Suite anteroom entrance along with both the north and south entrances of the CNC Hallway.

13.5.3.1 Washable mats will be cleaned daily or as needed. The mat can be cleaned with LpH, Vesphene or Peridox RTU and a squeegee.

13.5.4 Tacky mats must be changed as they become visibly soiled. Frequency of the tacky mat change is no less frequent than daily, and change may be required more frequently as needed.

13.5.5 Tacky mat changes are documented in Simplifi797®

Section Name: **Compounding**	Procedure Name: **Cleaning and Disinfection of the Sterile Suite**
Procedure #: **AHCT-SOP-0095**	Revision: 2 Effective Date: 14 Nov 2024

14.0 Conditions and Requirements for a Triple Clean

14.1 A Triple clean will be performed when the following conditions occur in the controlled environments:

14.1.1 After maintenance work performed in the Sterile Suite that severely compromises environmental integrity (ex. AC repairs, sanding, painting, etc.).

14.1.2 Before the first use and environmental testing of a new facility.

14.1.3 Power outages of greater than 59 minutes affecting the primary and secondary engineering controls.

14.1.4 For new equipment, prior to introduction into the controlled environments.

14.1.5 Equipment that has failed consecutive environmental monitoring samplings.

14.1.6 Loss of Differential Pressure.

14.1.7 After anyone enters the ISO 8 Sterile Corridor or higher classification without proper sterile gowning, excluding the two de-gowning rooms.

14.1.8 Additionally, at the discretion of the Microbiology Department.

14.2 A Triple clean will be performed using a sterile one-step cleaner and disinfectant (LpH or Vesphene) for the first two cleanings, then a designated sporicidal disinfectant used for the final cleaning (Peridox RTU or Spor Klenz). On the final cleaning, the sporicidal disinfectant is followed by 70% sIPA after the dwell-time is reached (see *Section 6.5* for dwell times).

14.2.1 **NOTE:** For every cleaning, all inside and outside surfaces of the PECs will be cleaned with sterile Peridox RTU.

14.3 The areas cleaned in a Triple Clean, unless otherwise noted, include all surfaces inside the PECs as well as all surfaces in the controlled environment (all activities of *Daily Cleaning and Disinfection (ISO 5, ISO 7, and ISO 8)*.

14.3.1 In addition, every surface area of all supplies, equipment, and inside and outside of bins will be cleaned

14.4 Perform and document in Simplifi797® all required cleaning

14.4.1 The task *Compounding Area – Triple Clean #1, Compounding Area – Triple Clean #2,* and *Compounding Area – Triple Clean #3* must be initiated before the start of the triple cleans to document that the cleaning was completed.

14.4.2 The Simplifi797® tasks and cleaning agents used will be documented at the completion of each of the cleans.

Date	Name	Action
8/30/2024	T. Zabinski	New SOP
10/22/24	T. Zabinski	Added 14.1.7 Additional requirement for a triple clean

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Document Number: AHCT-SOP-0095

Document Title: Cleaning and Disinfection of the Sterile Suite

Document Notes:

Document Information

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Signature Manifest

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Cleaning and Disinfection of the Sterile Suite

4: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	23 Oct 2024, 07:26:33 AM	Approved

5: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Pharmacy Ops	31 Oct 2024, 07:45:12 AM	Approved

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Section Name: **Common Pharmacy Work Instructions**	Work Instruction Name: **Visual Inspection**
Work Instruction #: **AHCT-WI-0031**	Revision: 2 Effective Date: 31 Mar 2022

1.0 Purpose

1.1 The purpose of this work instruction is to describe the process to follow when performing a visual inspection for particulate matter in vials, syringes or bags.

2.0 Scope

2.1 This applies to all technicians and pharmacists that are responsible for particulate checks on vials, syringes, or bags.

3.0 Responsibilities

3.1 The Pharmacy Manager or designee is responsible for ensuring that all affected employees receive training on this work instruction and that the instructions are adhered to.

4.0 Definitions

4.1 CSP – Compounded Sterile Preparation

5.0 Reference Documents

5.1 USP <788>

6.0 Equipment

6.1 Black/white light box

7.0 Instructions

7.1 Visual inspection of Vial units

7.1.1 Perform the physical unit inspection: Inspect one vial at a time for container/physical defects.

7.1.1.1 Note: For non-radioactive lyophilized CSPs – 10 vials per batch will be sent to a lab for USP <788> particulate testing.

7.1.2 Initially hold the vial at the cap and rotate the unit 360°, inspecting the entire circumference of the neck and body of the vial for any container defects (ie cracks, chipped material, loose glass, etc).

7.1.3 Then hold the vial upside down (cap side grasped by inspector's fingers and the bottom of the vial facing the inspector) to identify any container defects.

7.1.4 Finally, switch to holding the bottom of the vial, and then perform an inspection of the cap by rotating the unit 360° (grasped from the base of the vial by the inspector's fingers) until the entire cap circumference has been inspected.

7.1.5 Perform the inspection for particulate in the solution: Grasp the vial by the cap and gently swirl the solution (no not shake), trying not to create air bubble formation.

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7.1.6 Hold the vial still and inspect for 5 seconds in front of the white background, looking for floating and/or falling particulate matter. Remember to inspect from the bottom to top of the vial during this process.

7.1.7 Repeat this process for the vial in front of the black background.

7.1.8 Document any number of vials rejected on the batch record. Notify a supervisor if the number of vials rejected >10% of total batch for further investigation.

7.2 Visual inspection of Syringe units:

7.2.1 Perform the physical unit inspection: Inspect one syringe at a time for container/physical defects.

7.2.2 Initially hold the syringe at the plunger end and rotate the unit 360°, inspecting the tip and barrel of the syringe for any container defects (ie missing scale markings, chipped material, leaking plunger, etc).

7.2.3 Then perform an inspection of the cap by rotating the unit 360° (grasped from the base of the syringe by the inspector's fingers) until the entire cap circumference has been inspected.

7.2.4 Perform the inspection for particulate in the solution: Grasp the syringe at the plunger end and gently invert the unit. Return the syringe to an upright position (plunger grasped in inspector's fingers and cap facing up).

7.2.5 Hold the syringe still and inspect for 5 seconds in front of the white background, looking for any floating and/or falling particulate matter. Remember to inspect from the bottom to top of the syringe during this process.

7.2.6 Notify a supervisor if any defect is found for further investigation.

7.3 Visual inspection of Bags:

7.3.1 Perform the physical unit inspection: Inspect one bag at a time for container/physical defects.

7.3.2 Initially hold the bag at the top and rotate the unit 360°, inspecting the corners and ports for any container defects (ie leaking solution, unwanted marks on bag, etc).

7.3.3 Perform the inspection for particulate in the solution: Grasp the bag at the top and gently invert the unit. Return the bag to an upright position, looking for any floating and or/falling particulate matter. Remember to inspect from the bottom to top of the bag during this process.

7.3.4 Notify a supervisor if any defect is found for further investigation.

Date	Name	Action
1/18/2018	K. Yost	New Work Instruction
1/31/2019	K. Yost	Updated 7.1.1.1

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AHCT-WI-1016 Visual Inspection

4: Approval

Name/Signature	Title	Date	Meaning/Reason
Dennis Davis (DENNIS.DAVIS)	Director of Operations	01 Feb 2019, 07:02:53 AM	Approved
TJ Bresnahan (TJ.BRESNAHAN)	President Anazao Health	06 Feb 2019, 08:40:56 AM	Approved

5: Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Yost (KIMBERLY.YOST)	Quality Assurance Manager	07 Feb 2019, 06:14:17 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Abbie Oliver (ABBIE.OLIVER)	Quality Assurance	31 Mar 2022, 03:54:18 PM	Approved

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Calvin Buabeng, Kim Yost*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *Per Section 8.3 AHCT-SOP-0096 'Assignment of BUD's'*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13] *Sample label reviewed contains all elements as stated in question*	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *per sample label*	Yes
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *per SOP AHCT-SOP-0051 'Prescription Labeling'*	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *per sample CR*	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1] *Badge access*	Yes
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3] *Gloves Dermashield for non-HD sterile CSP's such as Semaglutide compounding*	Yes
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Purell Waterless surgical scrub*	Yes

STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Dermashield sterile gloves for non-HD compounding*	Yes
GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *Not currently compounding*	N/A
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	N/A
EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1] *Repeater pump outside hoods.*	N/A

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Not currently compounding-will be maintained in Simplify per task*	N/A
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *Pressure calibrated by MTA 10-25-24, temperature, humidity sensor calibration occurred in-house by QA tech : 9-16-24* *Other certificates of calibration available for VWR floor double door and Binder table top double door incubators 11-15-24* *Binder Dry heat ovens (Oven #9) calibrated 6-10-24* *Tuttnauer Autoclave calibrated dated 11-18-24* *Baxa Repeater pumps calibration by Plexus 8-26-24* *BI Incubator not currently noted or in place.* *SAS air samplers x 3 most recently calibrated 10-28-24*	Yes
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall vent returns*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Ceiling tiles caulked July 2024*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5]	Yes
CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5]	Yes

TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *Per Simplify*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *per Simplify*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3] *PEC locations: 8 horizontal flow hoods, 4 Air Clean powder hoods and 5 Nuaire vertical flow BSC's*	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0] *MTA Oct 25, 2024-new business* *8 horizontal flow hoods Germfree, 4 powder hoods and 5 vertical flow Nuaire Class II A2 BSC's (certified as ISO 5)*	Yes
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *MTA Oct 25, 2024*	Yes
ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4] *MTA Oct 25, 2024 certification-certifier has documented ACPH provided from HVAC for positive pressure room Sterile 1, 2 and 3 and Sterile ISO 5 room Mixing will occur in powder hoods in ISO 7*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Between 3 and 11 personnel documented by certifier*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Recorded -dated Nov 14, 2024*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0]	Yes
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2]	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *Oct 25, 2024 4 -certified Air Clean powder hoods -Hood 104, Hood 106-in Sterile 1 room, Hood 103 in Sterile 2, Hood 107 in Sterile 3*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *MTA report signed by Deisgnated Person KY*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3] *Pharmacy has a cleanroom suite to qualify the facility to compound Cat 2 and Cat 3 compounds*	Yes
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *Not currently compounding, but qualifies per SOP AHCT-SOP-0096 'Assignment of BUD's'*	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in tha absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *See above SOP*	N/A

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2] *Not currently compounding but does meet criteria for Cat 3 compounding, given full garbing of sterile PPE and the BUD's in SOP 0096*	N/A
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	Yes
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3] *Sterile coveralls*	Yes
[redacted] aseptically processed, sterility tested, and passing all applicable tests [redacted] tests) do not exceed the following BUDs: 60 days room temperature, 90 [redacted] chemical stability of the CSP is less than the maximum allowable [redacted] [redacted] *7-22-24 and almost to completion for assignment of 90 day BUD.* *Please provide final report to inspector.*	Yes
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	N/A
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2] *Available for bags, vials*	Yes
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by date obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3] *ARL studies provided for Sermorelin Inj 2mg/ml-Stability indicating assays initiated 7-22-24 and almost to completion for assignment of 90 day BUD. Please provide final report to inspector. Ongoing studies for Semaglutide inj.*	N/A
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4] *Sermorelin Inj lot 240716RA-716614 confirmed 10-17-24 per 90 day BUD by ARL labs*	Yes
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	Yes

STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *Articles sent follows SOP 0097 'Sterile Compounding Finished Preparation Testing'*	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *Not released product or compounded at this location.*	N/A
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3] *As confirmed for test batch Sermorelin Acetate 2mg/ml lot 240716RA-718614 from ARL labs demonstrating <10 EU/ml*	Yes
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	N/A
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3] *10-17-24 per ARL labs using USP <788> Method I*	Yes
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Started for Sermorelin and in process -please email inspector when completed at 90 day time point.*	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *per ARL labs based on vacuum decay*	Yes
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1]	Yes

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2] *per SOP AHCT-WI-0043 'Vial and Lyo Batch' -frequency is every 3 months*	Yes
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Available for SE*	Yes
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2]	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *SE demonstrated vials (#20 -50ml, #100-30ml and Lyo vial #130 10ml) 7-20-24 and bags 11-5-24 and syringes 9-6-24.*	Yes
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	Yes
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *Cat 3*	N/A
CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *Cat 3 section*	N/A
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *SE 3-28-24, CB 1/2024*	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ansure accurate and reproducible sampling. [USP 797 Section 6.1] *Completed by Microbiologist supervisor and training available for the 3 microbiology technicians* *In-house EMPQ air sampling binder.* *Air sampling will be daily in ISO 5,weekly ISO 7 surface sampling and air every other week for Air sampling in SEC's.*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *Initial for compounding personnel was completed 11/5/24*	N/A
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3] *Initial was completed 11/5/24 and will be on a 3 month cycle per SOP AHCT-WI-0043 'Vial and Lyo Batch Media Fill'*	N/A

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *AHCT-SOP-0093 'Environmental Monitoring Program for the Sterile Suite'* *Bi-weekly Air Sample, weekly surface sampling using Hardy TSA and SDA plates with L&T under dynamic conditions*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *In-house, most recent Oct 4, 2024, per EMPQ binder*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *SAS air samplers x 3 most recently calibrated 10-28-24 by Bioscience*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *Daily in ISO 5, weekly in ISO 7 and 8 and after each batch*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Dual plate method used -Hardy TSA with L&T plates P520 and Hardy SDA with L&T W70*	Yes
INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *In EMPQ binder*	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1] *per policy AHCT-SOP-0093 'Environmental Monitoring Program for the Sterile Suite'*	Yes
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	Yes
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2] *Weekly surface sampling plan and daily in ISO 5 and after the batch*	Yes

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7] *AHCT-SOP-0095 'Cleaning and Disinfection of the Sterile Suite'*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *11/5/24 for SE*	Yes
REUSABLE GARB: Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3]	Yes
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7] *Documented in Simplify*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *per detailed Simplify task*	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7] *10/31/24*	Yes
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes

CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Sterile LpH alternating evey other month with sterile Vesphene, Spor-Klenz (10 mins) and Sterile Peridox (3 mins)*	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1] *Includes Sterile sorb and Sturix lint free wipes*	Yes
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7].	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes
MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7] *Not currently compounding -last represented date 10-31-24 in Simplify*	N/A
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7] *As above*	N/A
CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7] *10-31-24*	Yes

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *CVE's located in ISO 7*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *AHCT-SOP-0074 'Active and Inactive Ingredient Selection' & AHCT-WI-0047 'Receiving Inventory'*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *Not currently compounding*	N/A
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *Ex Sermorelin from Biopeptek*	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similer conformance documentation is reviewed. [USP 797 Section 9.3.1] *Not currently compounding*	N/A
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2] *Documented in AHPS*	Yes
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	Yes
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identify, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3] *AHPS generates a barcode for the API used in the compound*	Yes

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview	Yes
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10] *Will be per SOP and initial sterilzation method will be filtration*	N/A
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10] *Has not formally compounded by terminal sterilization*	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *per sample CR -this is a quality check*	Yes

STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *No BI's at location yet, but will follow AHCT-WI-0019 'Use of the Tuttnauer Autoclave'*	N/A
CSP Sterilization by Filtration	Yes
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *Saint Gobain filters documented on sample CR*	N/A
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more then one time. [USP 797 Section 10.2] *per media fill CR.*	N/A
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *Not currently compounding. Will possibly prefilter Estradiol in the HD environment*	N/A
CSP Sterilization by Steam	No
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3]	N/A
CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3]	N/A
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3]	N/A
CSP Sterilization by Dry Heat *Possibly Testosterone and Estradiol inj*	Yes
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4] *June 13, 2024 for Binder Oven FED115 -available, but pharmacy has not compounded at this location yet*	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4] *Long term plans -not currently compounding*	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4] *Has not compounded yet*	N/A

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *IQ/OQ/PQ binder outlines the oven validation cycles*	Yes
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1]	N/A
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1] *Verified from ARL to demonstrate a 6.1 log reduction 6-19-24 - in Endotoxins using Charles River ECV's*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1]	Yes
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Designated team member-Supervising Pharmacist or designee*	Yes

MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Please add type of container closure-ex state sterile for the 10ml clear vials in the MFR for Sermorelin Acetate 2mg/ml, physical description is not stated on the MFR-ex clear colorless solution.* *Each CSP has a stability and potency test result referenced in the MFR*	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2] *Cat 3 compounder based on SOP's*	Yes
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)] *As per sample CR*	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Run is documented on the CR-which are housed in the log books*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *AHCT-SOP-0097 'Sterile Compounding Finished Preparation Testing'*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Section 6.4 of above SOP*	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *per QA 3 procedure AHCT-WI-0006 'QA3-AHPS'*	N/A
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Not currently compounding to dispense*	N/A
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *New business*	N/A

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1] *Next due 7/2025*	Yes
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1]	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *per AHCT-SOP-0016 'Quality Assurance Program'*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *AHCT-WI-0049 'Sterile Premix (Batches) Activation-Release Instructions'*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *Documented in Master Control AHCT-SOP-0018 'CAPA'*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *AHCT-SOP-0016 'Quality Assurance Program'*	Yes
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18] *Section 15 of above policy*	Yes
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1]	Yes

ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18] *New business-see Form 107*	N/A
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *New business Ongoing-different dates-please document Designated Person -per SOP 0001 'Policy on Policies'*	N/A
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	Yes
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20] *Has not formally initiated compounding yet*	N/A
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20]	Yes

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4] *Designated Person: Calvin Buabeng, Kim Yost*	Yes
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8] *AHCT-SOP-0040 'Hazardous Drug Employee Training and Safety Program'*	Yes
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2] *List represents the AoR*	Yes
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2] *Nov 14, 2024-in Master control*	Yes
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1] *5 BSC's*	Yes
HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17] *per AHCT-SOP-0040 'Hazardous Drug Employee Training and Safety Program'*	Yes
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5]	Yes
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1]	Yes
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10]	Yes
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2] *To be stored in HD Sterile 1 (ACPH 65) or 2 (ACPH of 59)*	N/A
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	N/A
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	N/A
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3] *Sterile HD 1 and Sterile HD 2 are 41 and 42 ACPH respectively per MTA Oct 2024 report*	Yes
C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3] *per Simplify*	Yes
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2] *Accessed via + pressure HD vestibule with documented as 42 from Oct 2024 MTA certification*	Yes
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	N/A
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2] *Eye wash station in ante room*	Yes

C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2] *All 5 BSC's are externally vented*	Yes
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressure in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specifiad recovery time has elapsed. [USP 800 Section 5.3] *On generator*	Yes
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	Yes
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1] *Esteem ASTM 6978 sterile gloves*	Yes
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	Yes
SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	Yes
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	Yes
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6] *Not currently compounding awaiting DEA permit*	N/A
INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17] *Awaiting DEA permit prior to initiating HD training*	N/A
ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9] *New business*	N/A
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	Yes
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	N/A
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2] *Awaiting DEA permit prior to initiating HD compounding*	N/A
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterile starting components are compounded insida a sterile suite. [USP 800 Section 5.3.2] *Pending receipt of DEA permit*	N/A
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	Yes
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3]	N/A
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15] *SOP followed is the Simplify task for D/D/C/D*	Yes
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15] *New business not currently compounding HD's -task in Simplify reflects D/D/C/D*	N/A
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15] *Other than Cleaning training forms, also stated in Critical point, Additional respirator use training documented*	Yes
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	Yes
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4] *Peridox and Spor Klenz*	Yes
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2] *Not currently compounding HD's -see Simplify task for daily cleaning*	N/A
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivatad, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2] *10/31/24 in Simplify*	Yes

DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15] *Not currently compounding HD's. Awaiting DEA permit then will place disposal bins*	N/A
LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2] *Courier: Fedex*	Yes
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Sections 11.1 & 13] *Not currently compounding HD's, sample label reviewed states hazardous drug-example Testosterone*	Yes
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	Yes
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	Yes
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16] *AHCT-WI-0123 'HD Spill Management'*	Yes
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16] *Spill kit in general pharmacy area*	Yes
SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16]	N/A
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17] *Clean Harbors*	Yes

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow eir at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained end available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer end at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	

Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(I) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Remarks:

Correct spelling of firm is Southeast Quality Pharmacy LLC.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:11/21/2024

Representative:

Calvin Buabeng

Data:11/21/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File # 30156
Insp # 200960

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTHEAST QUALITY PHARMACY, LLC		11/21/2024
DOING BUSINESS AS ANAZAOHEALTH		
STREET ADDRESS 5401 HANGAR COURT	**TELEPHONE #** 800-723-7455	**EXT**
CITY TAMPA	**COUNTY** HILLSBOROUGH	**STATE/ZIP** FL/33634

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

ACS Manager

Optional Information

Basic License Data - PSD

License Relations

RX DPT MGR/COR/POR

BUABENG, CALVIN BAAFI	License # 51078

INV797 - USP Sterile Compounding

A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Calvin Buabeng, Kim Yost*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A

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PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *Per Section 8.3 AHCT-SOP-0096 'Assignment of BUD's'*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2] *Not currently compounding, however SOP is to use stock solutions such as Baclofen within 6 hours of being punctured -as drawn up in syringes.*	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1] *All intrathecals are non-preserved*	N/A

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13] *Sample label reviewed contains all elements as stated in question*	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *per sample label*	Yes
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *Sample label per SOP AHCT-SOP-0051 'Prescription Labeling'*	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *per sample CR and QA 1, QA2, QA3 for intrathecal medications*	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1] *Badge access*	Yes
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3]	Yes
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Purell Waterless Surgical Scrub*	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Dermashield sterile gloves for non-HD compounding*	Yes
GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *Not currently compounding*	N/A
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	N/A
EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1] *Repeater pump outside hoods.*	N/A

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Not currently compounding-will be maintained in Simplify per task*	N/A

EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *Pressure calibrated by MTA 10-25-24, temperature, humidity sensor calibration occurred in-house by QA tech : 9-16-24* *Other certificates of calibration available for VWR floor double door and Binder table top double door incubators 11-15-24* *Binder Dry heat ovens (Oven #9) calibrated 6-10-24* *Tuttnauer Autoclave calibrated dated 11-18-24* *Baxa Repeater pumps calibration by Plexus 8-26-24* *BI Incubator not currently noted or in place.* *SAS air samplers x 3 most recently calibrated 10-28-24*	Yes
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS -- Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall vent returns*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctursa between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Ceiling tiles caulked July 2024*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5]	Yes
CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *per SImplify*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains e minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *per Simplify*	Yes
PEC LOCATION: PECs sre located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3] *PEC locations: 8 horizontal flow hoods, 4 Air Clean powder hoods and 5 Nuaire vertical flow BSC's*	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION -- ALL CATEGORIES

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0] *MTA Oct 25, 2024-new business* *8 horizontal flow hoods Germfree, 4 powder hoods and 5 vertical flow Nuaire Class II A2 BSC's (certified as ISO 5)*	Yes
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *MTA Oct 25, 2024*	Yes

ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4] *MTA Oct 25, 2024 certification-certifier has documented ACPH provided from HVAC for positive pressure room Sterile 1, 2 and 3 and Sterile ISO 5 room Mixing will occur in powder hoods in ISO 7*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Between 3 and 11 personnel documented by certifier*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Recorded -dated Nov 14, 2024*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0]	Yes
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2]	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *Oct 25, 2024 4 -certified Air Clean powder hoods -Hood 104, Hood 106-in Sterile 1 room, Hood 103 in Sterile 2, Hood 107 in Sterile 3*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *MTA report signed by Deisgnated Person KY*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3] *Pharmacy will be compounding patient-specific Intrathecal formulations such as Hydromorphone, Baclofen inj for pain in syringes or vials compounded from Category 3 stock solutions*	Yes
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *Examples of Cat 2 CSP's from non-sterile components will be assigned a 4 day BUD-Clonidine, Bupivacaine, Baclofen Intrathecal -under refrigeration*	N/A

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	

MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2] *Not currently compounding but does meet criteria for Cat 3 compounding, given full garbing of sterile PPE and the BUD's in SOP 0096*	N/A
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	Yes
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3] *Sterile coveralls*	Yes
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3] *ARL studies provided for Sermorelin Inj 2mg/ml-Stability indicating assays initiated 7-22-24 and almost to completion for assignment of 90 day BUD. Please provide final report to inspector.*	Yes
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3] *Not terminally sterilizing and aqueous intrathecal formulations*	N/A
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2] *Available for bags, vials, syringes*	Yes
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3] *Available for Baclofen and Clonidine intrathecal*	Yes
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4] *per ARL lab -available per batch -when compounding is initiated at this location using USP <71> compendial methods*	Yes
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2] *Available for Clonidine 5mg/ml Intrathecal Inj, Baclofen 4mg/ml Intrathecal Inj. -from ARL*	Yes
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *per SOP*	N/A
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	N/A
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3] *Awaiting DEA permit prior to compounding Intrathecal controlled substance CSP's.*	N/A
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in en official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3] *See ARL COA establishing Endotoxin limits as NMT 7EU/ml for Baclofen 4mg/ml and Clonidine 5mg/ml Intrathecal*	Yes
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3] *Available at this time for non-controlled intrathecal formulations from ARL labs (follows USP <788>)-this is a one time requirement for the formulation*	Yes
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Non-preserved intrathecals-not required*	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *Available for Clonidine 5mg/ml Inj 30ml in 50ml bag and Baclofen 4mg/ml Inj 100ml in 100ml bag by Intrathecal inj*	Yes
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A

MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1] *The intrathecals will be non-preserved and used within the BUD*	N/A

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2] *per SOP AHCT-WI-0043 'Vial and Lyo Batch' -frequency is every 3 months*	Yes
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Available for SE*	Yes
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2]	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3]	Yes
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	Yes
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *See Cat 3 section*	N/A
CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	N/A
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Critical Point SE 3-28-24, CB 1/2024*	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Completed by Microbiologist supervisor and training available for the 3 microbiology technicians* *In-house EMPQ air sampling binder.* *Air sampling will be daily in ISO 5,weekly ISO 7 surface sampling and air every other week for Air sampling in SEC's*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *New business, Initial for compounding personnel was completed 11/5/24*	N/A
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3] *New business -last media fill for SE was 11/2024*	N/A

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *AHCT-SOP-0093 'Environmental Monitoring Program for the Sterile Suite'* *Bi-weekly Air Sample, weekly surface sampling using Hardy TSA and SDA plates with L&T under dynamic conditions*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *In-house, most recent Oct 4, 2024, per EMPQ binder*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *SAS air samplers x 3 most recently calibrated 10-28-24 by Bioscience*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *Daily in ISO 5, weekly in ISO 7 and 8 and after each batch*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Dual plate method used -Hardy TSA with L&T plates P520 and Hardy SDA with L&T W70*	Yes

INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *In EMPQ Binder*	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1] *per policy AHCT-SOP-0093 'Environmental Monitoring Program for the Sterile Suite'*	Yes
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	Yes
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2] *Weekly surface sampling plan and daily in ISO 5 and after the batch*	Yes

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7] *AHCT-SOP-0095 'Cleaning and Disinfection of the Sterile Suite'*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *11/5/24 for SE*	Yes
REUSABLE GARB: Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3]	Yes
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7] *Documented in Simplify*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *per detailed Simplify task*	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7] *10/31/24*	Yes
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If e one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Sterile LpH alternating evey other month with sterile Vesphene, Spor-Klenz (10 mins) and Sterile Peridox (3 mins)*	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1] *Includes Sterile sorb and Sturix lint free wipes*	Yes
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7].	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low linL Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes
MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7] *Not currently compounding -last represented date 10-31-24 in Simplify*	N/A
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7] *As above*	Yes

CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7] *10/31/24*	Yes

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *CVE's located in ISO 7*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *AHCT-SOP-0074 'Active and Inactive Ingredient Selection' & AHCT-WI-0047 'Receiving Inventory'*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *Not currently compounding-will be USP NF*	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *Ex Baclofen USP from Letco COA from Medilux*	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *Syringes are BD/Mckesson, Vials are purchased sterile, tubing confirmed to be sterile*	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2] *No API noted at this location at this time*	N/A
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the data of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *No API at this location*	N/A
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identify, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3] *AHPS generates a barcode for the API used in the compound*	Yes

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview	Yes
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10] *Sterilization by filtration*	Yes
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10] *Has not formally compounded by terminal sterilization*	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10]	N/A
STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *No BI's at location yet, but will follow AHCT-WI-0019 'Use of the Tuttnauer Autoclave'*	N/A
CSP Sterilization by Filtration	Yes
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface araa. Filters ere chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *Saint Gobain PES filters*	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Has not compounded- reviewed media fill CR*	N/A
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *Has not compounded CS Intrathecals-awaits DEA permit*	N/A
CSP Sterilization by Steam	Yes
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3] *Not currently compounding but when DEA permit received, pharmacy plans on sterilizing aqueous solutions such as Hydromorphone for IT use. Pharmacy has a validation from a previous location for 3P Autoclave from June 26, 2024*	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3] *per policy AHCT-WI-0019 'Use of Tuttnauer Autoclave' chemical indicator 3M Comply used, has not initiated compounding*	N/A

CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3] *Sterilize twice aseptically and terminally for Intrathecals*	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3] *Distilled water*	Yes
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3] *Will be in binders*	N/A
CSP Sterilization by Dry Heat	No
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4]	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4]	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4]	N/A

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *IQ/OQ/PQ binder outlines the oven validation cycles*	Yes
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1]	N/A
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1]	Yes
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1] *Verified from ARL to demonstrate a 6.1 log reduction 6-19-24 - in Endotoxins using Charles River ECV's*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1]	Yes
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Designated team member-Supervising Pharmacist or designee*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Please indicate sterile bags*	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2]	Yes
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)]	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Run is documented on the CR-which are housed in the log books*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *AHCT-SOP-0097 'Sterile Compounding Finished Preparation Testing'*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Section 6.4 of above SOP*	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *per QA 3 procedure AHCT-WI-0006 'QA3-AHPS'*	Yes

CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Not currently compounding to dispense*	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *New business*	Yes

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1] *Next due 7/2025*	Yes
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1]	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *per AHCT-SOP-0016 'Quality Assurance Program'*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *AHCT-WI-0049 'Sterile Premix (Batches) Activation-Release Instructions'*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *Documented in Master Control AHCT-SOP-0018 'CAPA'*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *AHCT-SOP-0016 'Quality Assurance Program'*	Yes
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18] *Section 15 of above policy*	Yes
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws end regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1]	Yes
ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18] *New business-see Form 107*	Yes
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *New business Ongoing-different dates-please document Designated Person -per SOP 0001 'Policy on Policies'*	Yes
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	Yes
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20] *Has not formally initiated compounding yet*	Yes
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20]	Yes

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2]	
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD activa pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	

HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5]	
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1]	
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2]	
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA mainteins a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3]	
C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3]	
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2]	
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2]	
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressura in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1]	
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, ara long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	
SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6]	
INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2]	
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterila starting components are compounded inside a sterile suite. [USP 800 Section 5.3.2]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, gradualed cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	

NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3]	
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15]	
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15]	
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4]	
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2]	
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15]	
LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2]	
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Sections 11.1 & 13]	
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	
SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16]	
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	

In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for starility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.] *Has not dispensed CSP's yet*	N/A
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.] *No API at this location yet*	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(I) F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *in AHPS*	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05] *Awaiting DEA permit*	N/A
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	N/A
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04] *Awaiting DEA permit*	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *Awaiting DEA permit*	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.] *New business*	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	Yes
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.] *Awaiting DEA permit*	N/A
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *No API at this time* *Contracted wholesalers will be : Letco, Fagron, Medisca, PCCA*	N/A
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)] *Pharmacist on call 24/7*	Yes
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)] *Nothing provided yet but policies available*	N/A

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

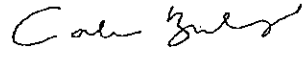
Inspector Signature

CULLIPHER, MALA

Data:11/21/2024

Representative:

Calvin Buabeng



Date:11/21/2024

AnazaoHealth Corporation ("Anazao") is the 100% owner of Southeast Quality Pharmacy, LLC (the applicant for this new pharmacy license). Anazao operates a 503B Outsourcing Facility located in Las Vegas, Nevada.

In July 2021, Anazao entered into a settlement agreement with the Ohio Board of Pharmacy regarding an Ohio-specific licensing issue. Anazao disputed OHBOP's assertions but consented to paying $2500 fine to settle the matter. A copy of the settlement agreement is attached. This matter has been closed by OHBOP.

Anazao reported the OHBOP settlement to all states in which it is licensed, including Hawaii. The Hawaii Board of Pharmacy initiated reciprocal discipline based on the Ohio settlement. This reciprocal discipline was not initiated due to an independent or separate act by Anazao. Instead, the reciprocal discipline was based solely on the Ohio settlement. Though Anazao disagreed with HIBOP's position, Anazao consented to paying a $500 fine to settle the matter. A copy of the Settlement Agreement and Payment Receipt received from HIBOP on June 21, 2022 is attached. This matter has been closed by HIBOP.

On June 29, 2022, Anazao entered into a settlement agreement with the Maine Board of Pharmacy. Anazao changed its Maine Pharmacist in Charge effective November 2, 2020. Anazao reported that change to MEBOP on November 13, 2020, which was 10 business days following the change. The applicable Maine rule in 2020 required PIC change reporting to be completed within 7 days, whereas Anazao mistakenly understood that reporting was required within 10 days. MEBOP sought discipline based on the late PIC change report. Anazao entered into a settlement with MEBOP and remitted the attached Settlement Agreement and $250 fine. This matter was subsequently closed by MEBOP. Anazao updated its policies and retrained personnel on appropriate report timing, which is currently 10 days in Maine.

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

July 11, 2022

Sent via email: coastlicensing@anazaohealth.com

AnazaoHealth Corporation
Attn: Hal Weaver, President
5710 Hoover Boulevard
Tampa, FL 33634-5339

Re: Complaint No. 2022-PHA-18213

Dear Mr. Weaver:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $250.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: Jennifer Willis, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Board Investigator
Kelly McLaughlin, Complainant

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
ANAZAOHEALTH CORPORATION	)	
	)	CONSENT AGREEMENT
Case No. 2022-PHA-18213	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order prescription pharmacy license of AnazaoHealth Corporation ("AnazaoHealth") in the State of Maine. The parties to this Consent Agreement are: AnazaoHealth , the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, AnazaoHealth was licensed by the Board as a mail order prescription pharmacy, license no. MO40001876, located at 7465 W Sunset Road, Suite 1200, Las Vegas, Nevada.

2. On November 1, 2020, Eric L. Sparks replaced Douglas F. Canmann as the pharmacist in charge ("PIC") of AnazaoHealth , thereby requiring AnazaoHealth to submit a Change of PIC application to the Board within 7 days after the PIC change.

3. AnazaoHealth , however, did not file a change of PIC application with the Board until November 13, 2020.

4. On April 5, 2022, Board Administrator, Geraldine Betts, filed an administrative complaint with the Board alleging that AnazaoHealth had failed to file a timely change of PIC application.

5. This administrative complaint was docketed as Case No. 2022-PHA-18213.

6. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order prescription pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

7. Pursuant to the Board's delegation of authority dated November 9, 2020, which authorizes Board Staff to offer prescribed consent agreements to resolve first-time violations of PIC change notification requirements, this Consent Agreement is being offered to finally resolve Case No. 2022-PHA-18213.

8. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Complaints Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035 by **May 13, 2022,** the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

9. AnazaoHealth admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

10. As DISCIPLINE for the violation admitted to in paragraph 9 above, AnazaoHealth agrees to accept the imposition of:

a. A WARNING; and

b. A CIVIL PENALTY in the amount of two hundred fifty dollars ($250.00). Payment of the civil penalty shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35

State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

11. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

12. Violation of any of the terms or conditions of this Consent Agreement by AnazaoHealth shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

13. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. The Board and AnazaoHealth agree that no further agency action will be initiated against AnazaoHealth 's license by the Board based upon the specific violations admitted to herein, except or unless AnazaoHealth fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against AnazaoHealth , and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving AnazaoHealth . The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against AnazaoHealth.

17. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved

electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

18. AnazaoHealth acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

AnazaoHealth Corporation

DATED: 6/30/2022

BY: _____
Authorized Representative

Douglas Camanagy
Printed Name

DATED: 7-7-22

_____
EDWARD J. KANE, President
Maine Board of Pharmacy

DATED: 7/8/2022

_____
ANDREW L. BLACK
Assistant Attorney General

DAVID Y. IGE
GOVERNOR

JOSH GREEN
LIEUTENANT GOVERNOR

CATHERINE P. AWAKUNI COLÓN
DIRECTOR
DEPARTMENT OF COMMERCE AND
CONSUMER AFFAIRS

ESTHER BROWN
COMPLAINTS AND
ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
TELEPHONE: (808) 586-2660
FAX: (808) 586-2670
cca.hawaii.gov/rico

HILO OFFICE
120 PAUAHI STREET, SUITE 212
HILO, HAWAII 96720

KONA OFFICE
HUALALAI CENTER
75-170 HUALALAI ROAD, SUITE C-309
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
2145 WELLS STREET, SUITE 106
MAILING ADDRESS
P.O. BOX 1049
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, SUITE 204
LIHUE, HAWAII 96766

June 22, 2022

TO: Fiscal Office
Attn: Jodee Saiki

RE: ANAZAOHEALTH CORPORATION
RICO Case No.: PHA 2021-60-L

Enclosed Via: ( ) Hand Delivery (X) **Inter-Office Mail** ( ) Messenger

TRANSMITTED HEREWITH:

( ) For Your Information	( ) For Correction
( ) For Signature & Return	(X) **For Payment**
( ) For Review & Comment	( ) Approved
( ) Per Your Request	( ) Disapproved
( ) For Appropriate Action	( ) For Your Files
( ) Per Our Conversation	(X) **See Remarks**

COPIES	DATE	DESCRIPTION
1	6/02/2022	Transaction Ref. # 000541069 depositing **$500.00 in the 999 FUND account.**

REMARKS: The Settlement Agreement in the above-referenced case was approved on June 16, 2022. Please **transfer $500.00** to the **CRF #C23 FUND**. Please feel free to contact me if you have any questions.

TOTAL FINE	$500.00
LESS PAYMENT	($500.00)
BALANCE DUE	**$ --0.00--**

PLEASE TRANSFER THE FUNDS FROM THE 999 FUND TO THE CRF #C23 FUND $500.00.

by: J. Fong
for IVY Y. E. KIM, Staff Attorney
Telephone: (808) 586-2660

c: Respondent
c: Carolyne Valbuena – PVL (via email)

STATE OF HAWAII
DEPT OF COMMERCE & CONSUMER AFFAIRS

OFFICIAL RECEIPT

Reference Number: 000541069

DATE: 6/02/2022

ACCOUNT:ANAZAOHEALTH CORPORATION

TRANSACTION LINES:

Cashier Code	Name	Amount
999	999 MISCELLANEOUS	$500.00

DESCRIPTION: (IEYK) PHA 2021-60-L; Anazaohealth Corporation; US Bank Money Order #9588005102 dated 05/04/2022 in the amount of $500.00 in full satisfaction of fine imposed in settlement agreement pending before the Board.

TOTAL FINE: $500.00
LESS Payment: <$500.00>
BALANCE DUE: - $0 -

c: Respondent
Carolyne Valbuena (PVL)

AMOUNT: $500.00

PAYMENT TYPE: Money Order

MEMO: T-902-1651-2408 TASK#: L54
RICO CASE#: PHA 2021-60-L
PAYOR: US BNAK **CHECK NUMBER:** 9588005102

CUSTOMER SIGNATURE: _____

PAYMENT COVER SHEET

L54 2408

ACCOUNT: ANAZAOHEALTH CORPORATION

TRANSACTION REF#: 000541069

TRANSACTION DATE: 5/25/2022

POSTED
JUN - 2 2022
DEPT. OF COMMERCE & CONSUMER AFFAIRS
STATE OF HAWAII

WORKITEM ID:

TRANSACTION LINES:

Cashier Code	Cashier Code Name	Amount
999	999 MISCELLANEOUS	$500.00

AMOUNT: $500.00

DESCRIPTION: (IEYK) PHA 2021-60-L; Anazaohealth Corporation; US Bank Money Order #9588005102 dated 05/04/2022 in the amount of $500.00 in full satisfaction of fine imposed in settlement agreement pending before the Board.

TOTAL FINE: $500.00
LESS Payment: <$500.00>
BALANCE DUE: - $0 -

c: Respondent
Carolyne Valbuena (PVL)

usbank. **PERSONAL MONEY ORDER** No. 9588005102

092-900
383

DATE: May 4, 2022

FIVE HUNDRED DOLLARS AND 00 CENTS

$ 500.00

Pay to the order of: DCCA - Compliance Resolution Fund

VOID IN EXCESS OF $1000.00

Purchaser, by signing, you agree to the service charge and other terms on the reverse side

NAME AnaZaoHealth Corporation

Location: 9588 Rainbow & Warm Springs Albertsons

U.S. Bank, National Association
Minneapolis, MN 55480

ADDRESS 7465 W Sunset Rd. Ste 120, Las Vegas, NV 89113

⑈958800510 2⑈ [redacted] [redacted]

1099

STATE OF OHIO
BOARD OF PHARMACY

February 25, 2021

AnazaoHealth Corporation
c/o Eric Sparks
7465 W. Sunset Rd, Suite 1200
Las Vegas, NV 89113

RE: Notice of Hearing /Settlement Agreement

Dear Mr. Sparks,

Enclosed are two documents; review them carefully. The first document is a Notice of Opportunity for Hearing, the second is a Settlement Agreement. Your rights to an administrative hearing are set forth in the first. You may avail yourself of these rights by following the instructions therein. If you choose, you may execute the second document and resolve the issues according to the terms set forth therein. Whichever you choose, you should do so after careful consideration.

Please Note: If you choose to execute the Settlement Agreement, the document should either be scanned and emailed as a PDF to legal@pharmacy.ohio.gov or mailed to **State of Ohio Board of Pharmacy 77 South High Street, 17th Floor Columbus, Ohio 43215-6108.** The Board cannot accept photographs taken of the settlement that are then emailed; sending your document as a JPG will only delay acceptance and processing of the Settlement Agreement. The Settlement Agreement becomes effective upon the date of the Board President's signature, at which time the terms of the Settlement Agreement will also become effective, and the Board-imposed fine (if applicable) will be attached to your license.

If you have questions about your options, you may call the Board office. The office will not give you legal advice. However, we will answer questions you have about the documents.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

Joseph A. Koltak /pac

Joseph Koltak, Esq

Senior Legal Counsel

Enclosures: Notice of Opportunity for Hearing
Settlement Agreement

CMRRR: 7020 3160 0000 6109 0748

STATE OF OHIO
BOARD OF PHARMACY

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: February 25, 2021
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE

IN THE MATTER OF:

CASE No. A-2019-0262
I-2019-0500

AnazaoHealth Corporation
c/o Eric Sparks
7465 W. Sunset Rd, Suite 1200
Las Vegas, NV 89113

License No. 012481000

February 25, 2021

Dear AnazaoHealth Corporation and Eric Sparks:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Wholesale Distributor of Dangerous Drugs under authority of Section 4729.56 of the Revised Code.

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to renew any registration certificate issued to a wholesale distributor of dangerous drugs (WDDD) pursuant to section 4729.52 of the Revised Code or may impose a monetary penalty of forfeiture not to exceed in the severity any fine designated under the Revised Code for a similar offense or $2,500 if the acts committed have not been classified as an offense by the Revised Code.

2. AnazaoHealth Corporation has a current WDDD license with the Board under license number 01-2481000, which lists Eric Sparks as the Responsible Person.

ALLEGATIONS

1. From on or about December 20, 2015 to on or about December 20, 2018, AnazaoHealth Corporation, located at 7465 W. Sunset Rd., Suite 1200, Las Vegas, Nevada, sold dangerous drugs, including controlled substances, to entities without a TDDD license with the Board and/or to entities without the proper Category TDDD license with the Board as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. AnazaoHealth Corporation sold to the following locations:

   a. Horizons Women's Healthcare, only a Category II TDDD license, located at 627 S. Edwin C Moses Blvd, 5th Floor Suite M, Dayton, Ohio.

b. Advanced Pain and Spine Institute, no TDDD license, located at 9600 Montgomery Road, Cincinnati, Ohio.

c. Body Shapes Medical-Cincinnati, only a Category II TDDD license, located at 11147 Montgomery Road, Suite 200, Cincinnati, Ohio.

d. Women's Comprehensive Health Center, no TDDD license, located at 135 N. Ewing Street, Suite 205, Lancaster, Ohio.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective September 29, 2017, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective April 6, 2017, September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A) of the ORC, as effective April 21, 2014 and February 1, 2016, Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1)(a) to (d), (f) to (h), and (l) to (p) of section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective October 5, 2015, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the Board's online registry to confirm licensure, each punishable by a maximum fine of $2,500 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

6. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2015, each violation punishable by a maximum fine of $2,500 if committed by an organization:

   a. Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2); and/or

   b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(4).

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, each violation punishable by a maximum penalty of $2,500: Is not of good moral character and habits.

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

CMRRR: 7020 3160 0000 6109 0748

Enclosure: Attachment A

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2019-0262
I-2019-0500

AnazaoHealth Corporation
c/o Eric Sparks
7465 E. Sunset Rd, Suite 1200
Las Vegas, NV 89113

License No. 01-2481000

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and AnazaoHealth Corporation, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of controlled substances to unlicensed entities and entities without the proper license. Together, the Board and AnazaoHealth Corporation are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. AnazaoHealth Corporation is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2481000, which lists Eric Sparks, as the Responsible Person.

FACTS

1. The Board initiated an investigation of AnazaoHealth Corporation, Wholesaler Distributor of Dangerous Drugs License No. 01-2481000, related to AnazaoHealth Corporation illegal sales of dangerous drugs to unlicensed entities and entities without the proper license.

2. On or about February 25, 2021, the Board sent a Notice of Opportunity for Hearing to AnazaoHealth Corporation, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. AnazaoHealth Corporation neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 25, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. AnazaoHealth Corporation agrees to pay to the Board a monetary penalty in the amount of $2,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. AnazaoHealth Corporation agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. AnazaoHealth Corporation agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by AnazaoHealth Corporation of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to AnazaoHealth Corporation by the Board and will NOT discharge AnazaoHealth Corporation from any obligation under the terms of this Agreement.

6. AnazaoHealth Corporation agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. AnazaoHealth Corporation understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom AnazaoHealth Corporation will operate.

9. AnazaoHealth Corporation waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Eric Sparks, on behalf of,
AnazaoHealth Corporation, Respondent

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

Date of Signature

Attachment A - Sales made by AnazaoHealth Corporation					
Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Advanced Pain and Spine Inst.	6/6/2018	4203383	Testosterone 200mg	1 pellet	17
Advanced Pain and Spine Inst.	8/30/2018	4272799	Testosterone 200mg	1 pellet	8
Advanced Pain and Spine Inst.	6/6/2018	4203382	Testosterone 100mg	1 pellet	23
Advanced Pain and Spine Inst.	6/26/2018	4218767	Testosterone 100mg	1 pellet	6
Advanced Pain and Spine Inst.	7/20/2018	4238677	Testosterone 100mg	1 pellet	20
Advanced Pain and Spine Inst.	7/26/2018	4243189	Testosterone 100mg	1 pellet	5
Advanced Pain and Spine Inst.	8/30/2018	4272798	Testosterone 100mg	1 pellet	30
Advanced Pain and Spine Inst.	6/6/2018	4203379	Testosterone 25mg	1 pellet	2
Advanced Pain and Spine Inst.	6/20/2018	4216066	Testosterone 25mg	1 pellet	3
Advanced Pain and Spine Inst.	6/26/2018	4218764	Testosterone 25mg	1 pellet	3
Advanced Pain and Spine Inst.	7/20/2018	4238674	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst.	7/26/2018	4243188	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst.	8/30/2018	4272795	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst.	6/6/2018	4203380	Testosterone 50mg	1 pellet	1
Advanced Pain and Spine Inst.	6/26/2018	4218765	Testosterone 50mg	1 pellet	2
Advanced Pain and Spine Inst.	7/20/2018	4238675	Testosterone 50mg	1 pellet	5
Advanced Pain and Spine Inst.	8/30/2018	4272796	Testosterone 50mg	1 pellet	2
Advanced Pain and Spine Inst.	6/6/2018	4203381	Testosterone 80mg	1 pellet	1
Advanced Pain and Spine Inst.	6/26/2018	4218766	Testosterone 80mg	1 pellet	2
Advanced Pain and Spine Inst.	7/20/2018	4238676	Testosterone 80mg	1 pellet	5
Advanced Pain and Spine Inst.	8/30/2018	4272797	Testosterone 80mg	1 pellet	5
Body Shapes Medical-Cincinnati	1/26/2016	3627652	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	2/2/2016	3650501	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660663	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660666	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3667354	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3668072	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3668075	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/23/2016	3698594	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2016	3703871	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/20/2016	3714865	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/29/2016	3721012	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/30/2016	3722277	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/6/2016	3724903	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/7/2016	3725539	Testosterone 100mg	1 pellet	16
Body Shapes Medical-Cincinnati	9/15/2016	3767058	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767068	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/29/2016	3775519	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/17/2016	3786327	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	11/8/2016	3801491	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2016	3805327	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2016	3806805	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807123	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807127	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826904	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826907	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/15/2016	3826911	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/6/2017	3838382	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/18/2017	3845957	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/30/2017	3852837	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/6/2017	3857327	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/10/2017	3861106	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2017	3873979	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/6/2017	3876304	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	3/9/2017	3878541	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/9/2017	3878543	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/28/2017	3891090	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903187	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903190	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/24/2017	3909585	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/27/2017	3912100	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/28/2017	3913556	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/1/2017	3914206	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/3/2017	3916899	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/9/2017	3921007	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/15/2017	3925279	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/24/2017	3931243	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2017	3935009	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3936871	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3937183	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/8/2017	3938583	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946393	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946397	Testosterone 100mg	1 pellet	1

Attachment A: Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Body Shapes Medical-Cincinnati	6/21/2017	3951911	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/26/2017	3953647	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/14/2017	3966321	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/14/2017	3966321	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/17/2017	3967192	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/27/2017	3975585	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/1/2017	3979290	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983032	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983035	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/14/2017	3987328	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/15/2017	3987693	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/25/2017	3995402	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/29/2017	3997320	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/6/2017	4002143	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/6/2017	4002146	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/8/2017	4003483	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/13/2017	4011808	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/6/2017	4025520	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/6/2017	4026599	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/13/2017	4029488	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/25/2017	4038720	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/1/2017	4043083	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/1/2017	4043308	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/10/2017	4050342	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/14/2017	4053298	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2017	4053766	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2017	4054737	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2017	4054741	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/1/2017	4065303	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/7/2017	4068068	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/11/2017	4071441	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/12/2017	4072352	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2016	3650849	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660864	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660867	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3667353	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3668070	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/23/2016	3698593	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2016	3702869	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/20/2016	3718866	Testosterone 37.5mg	1 pellet	2
Body Shapes Medical-Cincinnati	6/29/2016	3721859	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/30/2016	3722257	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/6/2016	3725093	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767060	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767063	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767071	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2016	3805328	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807139	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807128	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826901	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826904	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/18/2017	3845980	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/10/2017	3861107	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2017	3875059	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/9/2017	3875343	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/28/2017	3891091	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903183	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/24/2017	3909589	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/3/2017	3914206	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/3/2017	3915300	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/15/2017	3925278	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2017	3935457	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3936872	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3937160	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/13/2017	3946396	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/13/2017	3946398	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/26/2017	3954986	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/22/2017	3979291	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983036	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983036	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/14/2017	3987329	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/25/2017	3995104	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/29/2017	3997468	Testosterone 37.5mg	1 pellet	1

Attachment A - Sales made by AzurpharmHealth Corporation					
Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Body Shapes Medical-Cincinnati	8/6/2017	4002902	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/6/2017	4002894	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/8/2017	4005850	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/22/2017	4015219	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/6/2017	4025569	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/12/2017	4029489	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/1/2017	4043086	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/1/2017	4065305	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/30/2016	3752886	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	10/10/2016	3792518	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	12/15/2016	3825451	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	3/6/2017	3576104	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	6/21/2017	3950646	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	3/18/2016	3660674	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	5/23/2016	3699311	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	8/22/2016	3717342	Testosterone cypionate 200mg/ml	30ml	1
Horizona Women's Healthcare	1/15/2016	3621406	Testosterone 200mg	1 pellet	3
Horizona Women's Healthcare	2/9/2016	3636450	Testosterone 200mg	1 pellet	19
Horizona Women's Healthcare	1/18/2016	3543113	Testosterone 200mg	1 pellet	9
Horizona Women's Healthcare	2/22/2016	3644151	Testosterone 200mg	1 pellet	7
Horizona Women's Healthcare	3/11/2016	3657077	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	4/1/2016	3668462	Testosterone 200mg	1 pellet	2
Horizona Women's Healthcare	5/23/2016	3699464	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	6/14/2016	3711440	Testosterone 200mg	1 pellet	6
Horizona Women's Healthcare	7/15/2016	3750667	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	8/19/2016	3752249	Testosterone 200mg	1 pellet	22
Horizona Women's Healthcare	9/12/2016	3764571	Testosterone 200mg	1 pellet	9
Horizona Women's Healthcare	9/15/2016	3767181	Testosterone 200mg	1 pellet	22
Horizona Women's Healthcare	10/3/2016	3778607	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	10/14/2016	3785804	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	11/3/2016	3798493	Testosterone 200mg	1 pellet	5
Horizona Women's Healthcare	11/18/2016	3808777	Testosterone 200mg	1 pellet	18
Horizona Women's Healthcare	12/29/2016	3832729	Testosterone 200mg	1 pellet	13
Horizona Women's Healthcare	7/15/2017	3868653	Testosterone 200mg	1 pellet	8
Horizona Women's Healthcare	6/28/2017	3913378	Testosterone 200mg	1 pellet	12
Horizona Women's Healthcare	5/8/2017	3919668	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	5/23/2017	3930970	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	6/2/2017	3937477	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	7/27/2017	3977020	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	10/12/2017	4028469	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	11/1/2017	4051486	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	12/1/2017	4063510	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	12/8/2017	4068168	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	1/12/2018	4092505	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	1/26/2018	4107101	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	2/5/2018	4109021	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	3/20/2018	4120204	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	3/8/2018	4132320	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	4/6/2018	4155895	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	5/14/2018	4209351	Testosterone 200mg	1 pellet	26
Horizona Women's Healthcare	6/22/2018	4216844	Testosterone 200mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4229002	Testosterone 200mg	1 pellet	12
Horizona Women's Healthcare	7/10/2018	4230133	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	7/25/2018	4242299	Testosterone 200mg	1 pellet	30
Horizona Women's Healthcare	8/30/2018	4263218	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	7/28/2018	4269213	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	8/31/2018	4273332	Testosterone 200mg	1 pellet	10
Horizona Women's Healthcare	9/26/2018	4294081	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	9/26/2018	4295756	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	10/31/2018	4322776	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	11/7/2018	4329581	Testosterone 200mg	1 pellet	15
Horizona Women's Healthcare	11/29/2018	4347677	Testosterone 200mg	1 pellet	20
Horizona Women's Healthcare	1/12/2016	3618235	Testosterone 100mg	1 pellet	8
Horizona Women's Healthcare	2/16/2016	3641026	Testosterone 100mg	1 pellet	8
Horizona Women's Healthcare	3/11/2016	3657078	Testosterone 100mg	1 pellet	8
Horizona Women's Healthcare	4/5/2016	3671295	Testosterone 100mg	1 pellet	9
Horizona Women's Healthcare	4/28/2016	3685827	Testosterone 100mg	1 pellet	8
Horizona Women's Healthcare	5/23/2016	3699465	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	6/14/2016	3711435	Testosterone 100mg	1 pellet	5
Horizona Women's Healthcare	6/28/2016	3721136	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	7/29/2016	3740175	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	8/19/2016	3752242	Testosterone 100mg	1 pellet	15
Horizona Women's Healthcare	10/3/2016	3778601	Testosterone 100mg	1 pellet	10

Attachment A - Sales made by AnuzaHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Horizona Women's Healthcare	10/26/2016	3792878	Testosterone 10mg	1 pellet	10
Horizona Women's Healthcare	11/18/2016	3808770	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	12/29/2016	3832777	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	1/24/2017	3849129	Testosterone 100mg	1 pellet	6
Horizona Women's Healthcare	2/15/2017	3863552	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	3/14/2017	3881247	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	4/11/2017	3900229	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	5/8/2017	3919671	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	6/7/2017	3940358	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	7/10/2017	3962056	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	7/18/2017	3968166	Testosterone 100mg	1 pellet	6
Horizona Women's Healthcare	8/11/2017	3986068	Testosterone 100mg	1 pellet	30
Horizona Women's Healthcare	8/21/2017	3992994	Testosterone 100mg	1 pellet	40
Horizona Women's Healthcare	9/11/2017	4006351	Testosterone 100mg	1 pellet	30
Horizona Women's Healthcare	9/25/2017	4016275	Testosterone 100mg	1 pellet	20
Horizona Women's Healthcare	10/13/2017	4028108	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	11/1/2017	4043108	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	11/1/2017	4043716	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	12/13/2017	4075098	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	1/25/2018	4097503	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	2/15/2018	4117557	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	3/8/2018	4132332	Testosterone 100mg	1 pellet	8
Horizona Women's Healthcare	3/20/2018	4140339	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	4/12/2018	4157186	Testosterone 100mg	1 pellet	6
Horizona Women's Healthcare	5/8/2018	4174773	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	5/23/2018	4191357	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	6/22/2018	4216043	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	7/10/2018	4235093	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	8/9/2018	4254857	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	8/21/2018	4273128	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	9/26/2018	4294079	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	10/12/2018	4308871	Testosterone 100mg	1 pellet	15
Horizona Women's Healthcare	11/7/2018	4329586	Testosterone 100mg	1 pellet	10
Horizona Women's Healthcare	11/29/2018	4344618	Testosterone 100mg	1 pellet	15
Horizona Women's Healthcare	3/11/2016	3657079	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	4/5/2016	3671298	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	6/14/2016	3715419	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	7/29/2016	3740181	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	8/19/2016	3752246	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	10/3/2016	3778802	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3809771	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	1/24/2017	3848126	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881243	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900227	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	5/8/2017	3919620	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	7/10/2017	3962094	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	7/18/2017	3968167	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	9/11/2017	4006363	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	10/13/2017	4028464	Testosterone 25mg	1 pellet	4
Horizona Women's Healthcare	12/13/2017	4075014	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	2/5/2018	4109018	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140341	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	4/12/2018	4157190	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	5/8/2018	4174729	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	6/22/2018	4216043	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4226996	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	10/12/2018	4308870	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	10/31/2018	4337721	Testosterone 25mg	1 pellet	6
Horizona Women's Healthcare	1/13/2016	3619233	Testosterone 37.5mg	1 pellet	5
Horizona Women's Healthcare	2/16/2016	3661095	Testosterone 37.5mg	1 pellet	5
Horizona Women's Healthcare	4/29/2016	3695849	Testosterone 37.5mg	1 pellet	4
Horizona Women's Healthcare	6/14/2016	3715438	Testosterone 37.5mg	1 pellet	5
Horizona Women's Healthcare	8/19/2016	3752247	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3809770	Testosterone 37.5mg	1 pellet	5
Horizona Women's Healthcare	12/29/2016	3832778	Testosterone 37.5mg	1 pellet	7
Horizona Women's Healthcare	2/15/2017	3863554	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881246	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	6/7/2017	3940357	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2017	3962047	Testosterone 37.5mg	1 pellet	4
Horizona Women's Healthcare	8/11/2017	3986065	Testosterone 37.5mg	1 pellet	10
Horizona Women's Healthcare	10/12/2017	4028465	Testosterone 37.5mg	1 pellet	10
Horizona Women's Healthcare	11/13/2017	4059895	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	3/8/2018	4133323	Testosterone 37.5mg	1 pellet	6

Attachment A - Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Horizona Women's Healthcare	4/12/2018	4157188	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191354	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228992	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254964	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295752	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	10/12/2018	4308823	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329584	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618237	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641028	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/5/2016	3671296	Testosterone 50mg	1 pellet	1
Horizona Women's Healthcare	4/28/2016	3685816	Testosterone 50mg	1 pellet	5
Horizona Women's Healthcare	6/14/2016	3713434	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	7/29/2016	3740176	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792980	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3808773	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	12/20/2016	3832723	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	1/24/2017	3848127	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3861248	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900231	Testosterone 50mg	1 pellet	[redacted]
Horizona Women's Healthcare	7/10/2017	3962095	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	9/11/2017	3986085	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	10/17/2017	4028466	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	11/13/2017	4075010	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	2/15/2018	4117560	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140346	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/2/2018	4174726	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191355	Testosterone 50mg	1 pellet	4
Horizona Women's Healthcare	7/10/2018	4228995	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254953	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273330	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295758	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/31/2018	4322777	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329583	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618236	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641027	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	4/5/2016	3671297	Testosterone 87.5mg	1 pellet	4
Horizona Women's Healthcare	4/28/2016	3685821	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	6/14/2016	3713432	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	7/29/2016	3740177	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	8/19/2016	3752248	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792879	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3808774	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	1/24/2017	3848128	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881352	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900238	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	6/7/2017	3940190	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/18/2017	3988365	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	9/25/2017	4016256	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/13/2017	4028467	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	2/15/2018	4117558	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140345	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/12/2018	4157187	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	5/23/2018	4191353	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228993	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273336	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329582	Testosterone 87.5mg	1 pellet	6
Women's Comprehensive Health	4/25/2018	4169948	Anastrozole 1mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169947	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174147	Anastrozole 4mg/Testosterone 100mg	1 pellet	8
Women's Comprehensive Health	5/11/2018	4183771	Anastrozole 4mg/Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/6/2018	4202617	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	7/30/2018	4246525	Anastrozole 4mg/Testosterone 100mg	1 pellet	5
Women's Comprehensive Health	8/15/2018	4259698	Anastrozole 4mg/Testosterone 100mg	1 pellet	4
Women's Comprehensive Health	8/23/2018	4265829	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	9/18/2018	4287308	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322779	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	11/15/2018	4337599	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	4/18/2018	4164498	Anastrozole 4mg/Testosterone 60mg	1 pellet	1
Women's Comprehensive Health	6/6/2018	4202555	Anastrozole 4mg/Testosterone 60mg	1 pellet	4
Women's Comprehensive Health	6/18/2018	4217758	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	8/15/2018	4259699	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322780	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	11/15/2018	4337588	Anastrozole 4mg/Testosterone 60mg	1 pellet	2

Attachment A - Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Women's Comprehensive Health	6/6/2018	4202556	Avanti: 6gab 4mg/Testosterone 75mg	1 pellet	1
Women's Comprehensive Health	4/13/2018	4164499	Anastrozole 8mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	6/18/2018	4164561	Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169946	Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174143	Testosterone 100mg	1 pellet	12
Women's Comprehensive Health	5/11/2018	4184370	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212757	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/26/2018	4217896	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	7/17/2018	4236813	Testosterone 100mg	1 pellet	15
Women's Comprehensive Health	7/30/2018	4244520	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/15/2018	4253760	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265927	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	9/18/2018	4287296	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299217	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322426	Testosterone 100mg	1 pellet	15
Women's Comprehensive Health	11/15/2018	4337806	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/25/2018	4217897	Testosterone 12.5mg	1 pellet	1
Women's Comprehensive Health	7/30/2018	4244521	Testosterone 12.5mg	1 pellet	5
Women's Comprehensive Health	10/29/2018	4322431	Testosterone 12.5mg	1 pellet	1
[redacted] Comprehensive Health	6/25/2018	4217895	Testosterone 25mg	1 pellet	2
Women's Comprehensive Health	7/17/2018	4236814	Testosterone 25mg	1 pellet	3
Women's Comprehensive Health	7/30/2018	4244522	Testosterone 25mg	1 pellet	4
Women's Comprehensive Health	8/23/2018	4265832	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	9/18/2018	4287309	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	10/2/2018	4299218	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	10/23/2018	4322427	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	11/15/2018	4337807	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212753	Testosterone 37.5mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236816	Testosterone 37.5mg	1 pellet	5
Women's Comprehensive Health	7/30/2018	4244523	Testosterone 37.5mg	1 pellet	5
Women's Comprehensive Health	10/29/2018	4322430	Testosterone 37.5mg	1 pellet	1
Women's Comprehensive Health	6/18/2018	4212754	Testosterone 50mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236818	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	7/30/2018	4244524	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265834	Testosterone 50mg	1 pellet	4
Women's Comprehensive Health	9/18/2018	4287307	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299220	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322428	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	11/15/2018	4337804	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	4/25/2018	4169945	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174149	Testosterone 80mg	1 pellet	2
Women's Comprehensive Health	5/11/2018	4183269	Testosterone 80mg	1 pellet	2
Women's Comprehensive Health	6/18/2018	4212756	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236815	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	8/23/2018	4265831	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	10/2/2018	4299219	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	10/29/2018	4322429	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	11/15/2018	4337803	Testosterone 80mg	1 pellet	1

Douglas Cammann

~~Eric Sparks~~, on behalf of,
AnazaoHealth Corporation, Respondent

7/28/21
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Rich Miller, RPh, President, State
of Ohio Board of Pharmacy

7/29/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

7/29/2021
Date of Signature

9. AnazaoHealth Corporation waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. AnazaoHealth Corporation neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 25, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. AnazaoHealth Corporation agrees to pay to the Board a monetary penalty in the amount of $2,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. AnazaoHealth Corporation agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. AnazaoHealth Corporation agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by AnazaoHealth Corporation of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to AnazaoHealth Corporation by the Board and will NOT discharge AnazaoHealth Corporation from any obligation under the terms of this Agreement.

6. AnazaoHealth Corporation agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. AnazaoHealth Corporation understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom AnazaoHealth Corporation will operate.

STATE OF OHIO
BOARD OF PHARMACY

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2021 AUG -4 A 9:07
DEPT OF COMMERCE
& COMMISSIONER OF PHARMACY
STATE OF OHIO

IN THE MATTER OF:

CASE NO. A-2019-0262
I-2019-0500

AnazaoHealth Corporation
c/o Eric Sparks
7465 E. Sunset Rd, Suite 1200
Las Vegas, NV 89113

License No. 01-2481000

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and AnazaoHealth Corporation, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of controlled substances to unlicensed entities and entities without the proper license. Together, the Board and AnazaoHealth Corporation are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. AnazaoHealth Corporation is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2481000, which lists Eric Sparks, as the Responsible Person.

FACTS

1. The Board initiated an investigation of AnazaoHealth Corporation, Wholesaler Distributor of Dangerous Drugs License No. 01-2481000, related to AnazaoHealth Corporation illegal sales of dangerous drugs to unlicensed entities and entities without the proper license.

2. On or about February 25, 2021, the Board sent a Notice of Opportunity for Hearing to AnazaoHealth Corporation, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF ANAZAOHEALTH CORPORATION; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; RICO CASE NO. PHA 2021-60-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chairperson	June 16, 2022 DATE
Julie Takishima-Lacasa JULIE YURIE TAKISHIMA-LACASA Vice Chairperson	PATRICK ADAMS
Mark Brown MARK BROWN	CATALINA CROSS
Kent Kikuchi KENT KIKUCHI	Sheri Tokumaru SHERI TOKUMARU

PVL 7/6/21

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Las Vegas (City), Nevada (State), 05/11/2022 (Date).

ANAZAOHEALTH CORPORATION
Respondent

By: _____ (Signature)

Douglas Cammann (Print Name)

Its VP of Operations (Print Title)

DATED: Honolulu, Hawaii, 5/18/2022.

_____

IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2021-60-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's

3. On or about July 29, 2021, Respondent entered into a Settlement Agreement with the State of Ohio Board of Pharmacy in Case No. A-2019-0262, I-2019-0500 (hereinafter "Ohio Settlement Agreement"). The Ohio Settlement Agreement is attached hereto as Exhibit "1". The Ohio Settlement Agreement was based on an allegation that Respondent illegally sold dangerous drugs to unlicensed entities and entities without the proper license.

4. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

5. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibit "1" is a true and correct copy of the Ohio Settlement Agreement.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

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LICENSING DIVISION

2022 MAY 20 A 11: 39

DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorney for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

eFiled 6/20/2022 3:59 pm

HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of	)	PHA 2021-60-L
	)	
	)	SETTLEMENT AGREEMENT PRIOR TO
ANAZAOHEALTH CORPORATION,	)	FILING OF PETITION FOR DISCIPLINARY
	)	ACTION AND BOARD'S FINAL ORDER;
Respondent.	)	EXHIBIT "1"
	)	
	)	
	)	

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent ANAZAOHEALTH CORPORATION. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under the permit number PMP-558. The permit was issued on or about March 7, 2008. The permit will expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 7465 West Sunset Road, Suite 1200, Las Vegas, Nevada 89113.

I HEREBYCERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

ARION R. CLAGGETT
ACTING COMMISSIONER

BY ORDER:
STATE BOARD OF PHARMACY

THERESA M. TALBOTT, R.PH.
CHAIRPERSON

Respondent's Address:
Tracking # 9489 0090 0027 6582 3573 78

Anazaohealth Corporation
7465 W Sunset Rd, STE 1200
Las Vegas, NV 89113

Prosecuting Attorney: Ray J. Michalowski, Esquire

Board Counsel: Ariel E. O'Malley, Esquire

Date of Mailing: December 21, 2023

DOS Prothonotary:
Dec 20 2023

1125

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania,	:	
Bureau of Professional and	:	
Occupational Affairs	:	
v.	:	**Case No. 21-54-014780**
Anazaohealth Corporation,	:	
Respondent		

FINAL ORDER

AND NOW, this 20th day of December, 2023, the State Board of Pharmacy, having duly met and reviewed the entire record and upon consideration of the foregoing findings of fact, conclusions of law, and discussion, hereby **ORDERS** that Respondent Anazaohealth Corporation, registration number NP000601, be **PUBLICLY REPRIMANDED** and **IMPOSES** a **CIVIL PENALTY** of $2,000.00.

Respondent shall pay the full amount of the civil penalty by certified check, cashier's check, attorney's check or U.S. postal money order made payable to "Commonwealth of Pennsylvania." On or before thirty (30) days after the date of mailing indicated below, the full amount of the civil penalty shall be delivered to:

Board Counsel
Bureau of Professional and Occupational Affairs
P.O. Box 69523
Harrisburg, PA 17106-9523

Failure to pay the civil penalty within thirty (30) days will result in the immediate suspension of Respondent's registration until the civil penalty is paid in full.

This Order is effective immediately. The sanction shall take effect thirty (30) days from the date of mailing of this Order, namely January 22, 2024.

DOS Prothonotary:
Dec 20 2023
1126

STATE OF OHIO
BOARD OF PHARMACY

February 25, 2021

AnazaoHealth Corporation
c/o Eric Sparks
7465 W. Sunset Rd, Suite 1200
Las Vegas, NV 89113

RE: Notice of Hearing /Settlement Agreement

Dear Mr. Sparks,

Enclosed are two documents; review them carefully. The first document is a Notice of Opportunity for Hearing, the second is a Settlement Agreement. Your rights to an administrative hearing are set forth in the first. You may avail yourself of these rights by following the instructions therein. If you choose, you may execute the second document and resolve the issues according to the terms set forth therein. Whichever you choose, you should do so after careful consideration.

Please Note: If you choose to execute the Settlement Agreement, the document should either be scanned and emailed as a PDF to legal@pharmacy.ohio.gov or mailed to **State of Ohio Board of Pharmacy 77 South High Street, 17th Floor Columbus, Ohio 43215-6108.** The Board cannot accept photographs taken of the settlement that are then emailed; sending your document as a JPG will only delay acceptance and processing of the Settlement Agreement. The Settlement Agreement becomes effective upon the date of the Board President's signature, at which time the terms of the Settlement Agreement will also become effective, and the Board-imposed fine (if applicable) will be attached to your license.

If you have questions about your options, you may call the Board office. The office will not give you legal advice. However, we will answer questions you have about the documents.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

Joseph A. Koltak /pse

Joseph Koltak, Esq

Senior Legal Counsel

Enclosures: Notice of Opportunity for Hearing
Settlement Agreement

CMRRR: 7020 3160 0000 6109 0748

PAYMENT COVER SHEET

L54 2408

ACCOUNT: ANAZAOHEALTH CORPORATION

TRANSACTION REF#: 000541069

TRANSACTION DATE: 5/25/2022

WORKITEM ID:

TRANSACTION LINES:

POSTED
JUN - 2 2022
DEPT. OF COMMERCE & CONSUMER AFFAIRS
STATE OF HAWAII

Cashier Code	Cashier Code Name	Amount
999	999 MISCELLANEOUS	$500.00

AMOUNT: $500.00

DESCRIPTION: (IEYK) PHA 2021-60-L; Anazaohealth Corporation; US Bank Money Order #9588005102 dated 05/04/2022 in the amount of $500.00 in full satisfaction of fine imposed in settlement agreement pending before the Board.

TOTAL FINE: $500.00
LESS Payment: <$500.00>
BALANCE DUE: - $0 -

c: Respondent
Carolyne Valbuena (PVL)

usbank. **PERSONAL MONEY ORDER** No. 9588005102

092-900
383

DATE: May 4, 2022

FIVE HUNDRED DOLLARS AND 00 CENTS

$ 500.00

Pay to the order of: DCCA - Compliance Resolution Fund

VOID IN EXCESS OF $1000.00

Purchaser, by signing, you agree to the service charge and other terms on the reverse side

NAME AnazaoHealth Corporation

ADDRESS 7465 W Sunset Rd Ste 120, Las Vegas, NV 89113

Location: 9588 Rainbow & Warm Springs Albertsons
U.S. Bank, National Association
Minneapolis, MN 55480

⑈958800510 2⑈ [redacted] [redacted]

STATE OF HAWAII
DEPT OF COMMERCE & CONSUMER AFFAIRS

OFFICIAL RECEIPT

Reference Number: 000541069

DATE: 6/02/2022

ACCOUNT:ANAZAOHEALTH CORPORATION

TRANSACTION LINES:

Cashier Code	Name	Amount
999	999 MISCELLANEOUS	$500.00

DESCRIPTION: (IEYK) PHA 2021-60-L; Anazaohealth Corporation; US Bank Money Order #9588005102 dated 05/04/2022 in the amount of $500.00 in full satisfaction of fine imposed in settlement agreement pending before the Board.

TOTAL FINE: $500.00
LESS Payment: <$500.00>
BALANCE DUE: - $0 -

c: Respondent
Carolyne Valbuena (PVL)

AMOUNT: $500.00

PAYMENT TYPE: Money Order

MEMO: T-902-1651-2408 TASK#: L54
RICO CASE#: PHA 2021-60-L
PAYOR: US BNAK **CHECK NUMBER:** 9588005102

CUSTOMER SIGNATURE: _____

DAVID Y. IGE
GOVERNOR

JOSH GREEN
LIEUTENANT GOVERNOR

CATHERINE P. AWAKUNI COLÓN
DIRECTOR
DEPARTMENT OF COMMERCE AND
CONSUMER AFFAIRS

ESTHER BROWN
COMPLAINTS AND
ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
TELEPHONE: (808) 586-2660
FAX: (808) 586-2670
cca.hawaii.gov/rico

HILO OFFICE
120 PAUAHI STREET, SUITE 212
HILO, HAWAII 96720

KONA OFFICE
HUALALAI CENTER
75-170 HUALALAI ROAD, SUITE C-309
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
2145 WELLS STREET, SUITE 106
MAILING ADDRESS
P.O. BOX 1049
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, SUITE 204
LIHUE, HAWAII 96766

June 22, 2022

TO: Fiscal Office
Attn: Jodee Saiki

RE: ANAZAOHEALTH CORPORATION
RICO Case No.: PHA 2021-60-L

Enclosed Via: ( ) Hand Delivery (X) **Inter-Office Mail** ( ) Messenger

TRANSMITTED HEREWITH:

( )	For Your Information	( )	For Correction
( )	For Signature & Return	(X)	**For Payment**
( )	For Review & Comment	( )	Approved
( )	Per Your Request	( )	Disapproved
( )	For Appropriate Action	( )	For Your Files
( )	Per Our Conversation	(X)	**See Remarks**

COPIES	DATE	DESCRIPTION
1	6/02/2022	Transaction Ref. # 000541069 depositing **$500.00 in the 999 FUND account.**

REMARKS: The Settlement Agreement in the above-referenced case was approved on June 16, 2022. Please **transfer $500.00** to the **CRF #C23 FUND.** Please feel free to contact me if you have any questions.

TOTAL FINE	$500.00
LESS PAYMENT	($500.00)
BALANCE DUE	**$ --0.00--**

PLEASE TRANSFER THE FUNDS FROM THE 999 FUND TO THE CRF #C23 FUND $500.00.

by: J. Fong
for IVY Y. E. KIM, Staff Attorney
Telephone: (808) 586-2660

c: Respondent
c: Carolyne Valbuena – PVL (via email)

electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

18. AnazaoHealth acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

AnazaoHealth Corporation

DATED: 6/30/2022

BY: [signature]
Authorized Representative

Douglas Cammann
Printed Name

DATED: 7-7-22

[signature]
EDWARD J. KANE, President
Maine Board of Pharmacy

DATED: 7/8/2022

[signature]
ANDREW L. BLACK
Assistant Attorney General

State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

11. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

12. Violation of any of the terms or conditions of this Consent Agreement by AnazaoHealth shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

13. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. The Board and AnazaoHealth agree that no further agency action will be initiated against AnazaoHealth 's license by the Board based upon the specific violations admitted to herein, except or unless AnazaoHealth fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against AnazaoHealth , and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving AnazaoHealth . The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against AnazaoHealth.

17. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved

5. This administrative complaint was docketed as Case No. 2022-PHA-18213.

6. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order prescription pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

7. Pursuant to the Board's delegation of authority dated November 9, 2020, which authorizes Board Staff to offer prescribed consent agreements to resolve first-time violations of PIC change notification requirements, this Consent Agreement is being offered to finally resolve Case No. 2022-PHA-18213.

8. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Complaints Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035 by **May 13, 2022,** the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

9. AnazaoHealth admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

10. As DISCIPLINE for the violation admitted to in paragraph 9 above, AnazaoHealth agrees to accept the imposition of:

a. A WARNING; and

b. A CIVIL PENALTY in the amount of two hundred fifty dollars ($250.00). Payment of the civil penalty shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
ANAZAOHEALTH CORPORATION	)	
	)	CONSENT AGREEMENT
Case No. 2022-PHA-18213	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order prescription pharmacy license of AnazaoHealth Corporation ("AnazaoHealth") in the State of Maine. The parties to this Consent Agreement are: AnazaoHealth , the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, AnazaoHealth was licensed by the Board as a mail order prescription pharmacy, license no. MO40001876, located at 7465 W Sunset Road, Suite 1200, Las Vegas, Nevada.

2. On November 1, 2020, Eric L. Sparks replaced Douglas F. Canmann as the pharmacist in charge ("PIC") of AnazaoHealth , thereby requiring AnazaoHealth to submit a Change of PIC application to the Board within 7 days after the PIC change.

3. AnazaoHealth , however, did not file a change of PIC application with the Board until November 13, 2020.

4. On April 5, 2022, Board Administrator, Geraldine Betts, filed an administrative complaint with the Board alleging that AnazaoHealth had failed to file a timely change of PIC application.

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

July 11, 2022

Sent via email: coastlicensing@anazaohealth.com

AnazaoHealth Corporation
Attn: Hal Weaver, President
5710 Hoover Boulevard
Tampa, FL 33634-5339

Re: Complaint No. 2022-PHA-18213

Dear Mr. Weaver:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $250.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: Jennifer Willis, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Board Investigator
Kelly McLaughlin, Complainant

Douglas Cammann

~~Eric Sparks~~, on behalf of,
AnazaoHealth Corporation, Respondent

7/24/21
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Rich Miller, RPh, President, State
of Ohio Board of Pharmacy

7/29/2021
Date of Signature

Henry G. Appel, Ohio Assistant Attorney General

7/29/2021
Date of Signature

9. AnazaoHealth Corporation waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. AnazaoHealth Corporation neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 25, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. AnazaoHealth Corporation agrees to pay to the Board a monetary penalty in the amount of $2,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. AnazaoHealth Corporation agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. AnazaoHealth Corporation agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by AnazaoHealth Corporation of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to AnazaoHealth Corporation by the Board and will NOT discharge AnazaoHealth Corporation from any obligation under the terms of this Agreement.

6. AnazaoHealth Corporation agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. AnazaoHealth Corporation understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom AnazaoHealth Corporation will operate.

STATE OF OHIO
BOARD OF PHARMACY

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2021 AUG -4 A 9:07
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF OHIO

IN THE MATTER OF:

CASE NO. A-2019-0262
I-2019-0500

AnazaoHealth Corporation
c/o Eric Sparks
7465 E. Sunset Rd, Suite 1200
Las Vegas, NV 89113

License No. 01-2481000

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and AnazaoHealth Corporation, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of controlled substances to unlicensed entities and entities without the proper license. Together, the Board and AnazaoHealth Corporation are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. AnazaoHealth Corporation is a licensed Wholesaler Distributor of Dangerous Drug, License No. 01-2481000, which lists Eric Sparks, as the Responsible Person.

FACTS

1. The Board initiated an investigation of AnazaoHealth Corporation, Wholesaler Distributor of Dangerous Drugs License No. 01-2481000, related to AnazaoHealth Corporation illegal sales of dangerous drugs to unlicensed entities and entities without the proper license.

2. On or about February 25, 2021, the Board sent a Notice of Opportunity for Hearing to AnazaoHealth Corporation, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF ANAZAOHEALTH CORPORATION; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; RICO CASE NO. PHA 2021-60-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chairperson	June 16, 2022 DATE
Julie Takishima-Lacasa JULIE YURIE TAKISHIMA-LACASA Vice Chairperson	PATRICK ADAMS
Mark Brown MARK BROWN	CATALINA CROSS
Kent Kikuchi KENT KIKUCHI	Sheri Tokumaru SHERI TOKUMARU

PVL 7/6/21

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Las Vegas (City), Nevada (State), 05/11/2022 (Date).

ANAZAOHEALTH CORPORATION
Respondent

By: _____ (Signature)
Douglas Cammann (Print Name)
Its VP of Operations (Print Title)

DATED: Honolulu, Hawaii, 5/18/2022.

_____
IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2021-60-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's

3. On or about July 29, 2021, Respondent entered into a Settlement Agreement with the State of Ohio Board of Pharmacy in Case No. A-2019-0262, I-2019-0500 (hereinafter "Ohio Settlement Agreement"). The Ohio Settlement Agreement is attached hereto as Exhibit "1". The Ohio Settlement Agreement was based on an allegation that Respondent illegally sold dangerous drugs to unlicensed entities and entities without the proper license.

4. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

5. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibit "1" is a true and correct copy of the Ohio Settlement Agreement.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION

2022 MAY 20 A 11:39

DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorney for Department of Commerce and Consumer Affairs

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

eFiled 6/20/2022 3:59 pm

HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of	)	PHA 2021-60-L
ANAZAOHEALTH CORPORATION,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"
Respondent.	)	

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent ANAZAOHEALTH CORPORATION. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under the permit number PMP-558. The permit was issued on or about March 7, 2008. The permit will expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 7465 West Sunset Road, Suite 1200, Las Vegas, Nevada 89113.

I HEREBYCERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

ARION R. CLAGGETT
ACTING COMMISSIONER

BY ORDER:
STATE BOARD OF PHARMACY

THERESA M. TALBOTT, R.PH.
CHAIRPERSON

Respondent's Address:
Tracking # 9489 0090 0027 6582 3573 78

Anazaohealth Corporation
7465 W Sunset Rd, STE 1200
Las Vegas, NV 89113

Prosecuting Attorney: Ray J. Michalowski, Esquire

Board Counsel: Ariel E. O'Malley, Esquire

Date of Mailing: December 21, 2023

DOS Prothonotary:
Dec 20 2023

1146

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania,	:	
Bureau of Professional and	:	
Occupational Affairs	:	
v.	:	**Case No. 21-54-014780**
Anazaohealth Corporation,	:	
Respondent		

FINAL ORDER

AND NOW, this 20th day of December, 2023, the State Board of Pharmacy, having duly met and reviewed the entire record and upon consideration of the foregoing findings of fact, conclusions of law, and discussion, hereby **ORDERS** that Respondent Anazaohealth Corporation, registration number NP000601, be **PUBLICLY REPRIMANDED** and **IMPOSES** a **CIVIL PENALTY** of $2,000.00.

Respondent shall pay the full amount of the civil penalty by certified check, cashier's check, attorney's check or U.S. postal money order made payable to "Commonwealth of Pennsylvania." On or before thirty (30) days after the date of mailing indicated below, the full amount of the civil penalty shall be delivered to:

Board Counsel
Bureau of Professional and Occupational Affairs
P.O. Box 69523
Harrisburg, PA 17106-9523

Failure to pay the civil penalty within thirty (30) days will result in the immediate suspension of Respondent's registration until the civil penalty is paid in full.

This Order is effective immediately. The sanction shall take effect thirty (30) days from the date of mailing of this Order, namely January 22, 2024.

DOS Prothonotary:
Dec 20 2023

1147

Attachment A - Sales made by Anacaothealth Corporaten					
Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Women's Comprehensive Health	6/6/2018	4207556	Anastrozole 4mg/Testosterone 75mg	1 pellet	1
Women's Comprehensive Health	4/19/2018	4164492	Anastrozole 8mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	4/18/2018	4164501	Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169946	Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	5/1/2018	4174148	Testosterone 100mg	1 pellet	12
Women's Comprehensive Health	5/11/2018	4183270	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212757	Testosterone 100mg	1 pellet	6
Women's Comprehensive Health	6/25/2018	4217896	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	7/11/2018	4236813	Testosterone 100mg	1 pellet	15
Women's Comprehensive Health	7/30/2018	4244570	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/15/2018	4258700	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265837	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	9/18/2018	4287286	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299217	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322426	Testosterone 100mg	1 pellet	13
Women's Comprehensive Health	11/15/2018	4337606	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/25/2018	4217897	Testosterone 12.5mg	1 pellet	4
Women's Comprehensive Health	7/30/2018	4244521	Testosterone 12.5mg	1 pellet	9
Women's Comprehensive Health	10/29/2018	4322441	Testosterone 12.5mg	1 pellet	7
[redacted]	6/25/2018	4217895	Testosterone 25mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4238814	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	7/30/2018	4244527	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	8/23/2018	4265832	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	9/18/2018	4287309	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	10/2/2018	4299218	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322427	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	11/15/2018	4337607	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212752	Testosterone 37.5mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236816	Testosterone 37.5mg	1 pellet	3
Women's Comprehensive Health	7/30/2018	4244523	Testosterone 37.5mg	1 pellet	5
Women's Comprehensive Health	10/29/2018	4322439	Testosterone 37.5mg	1 pellet	1
Women's Comprehensive Health	6/18/2018	4212754	Testosterone 50mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236818	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	7/30/2018	4244524	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265834	Testosterone 50mg	1 pellet	6
Women's Comprehensive Health	9/18/2018	4287307	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299220	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322428	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	11/15/2018	4337604	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	4/25/2018	4169945	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174149	Testosterone 80mg	1 pellet	2
Women's Comprehensive Health	5/11/2018	4183269	Testosterone 80mg	1 pellet	2
Women's Comprehensive Health	6/18/2018	4212756	Testosterone 80mg	1 pellet	3
Women's Comprehensive Health	7/17/2018	4236819	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	8/23/2018	4265831	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	10/2/2018	4299219	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	10/29/2018	4322429	Testosterone 80mg	1 pellet	3
Women's Comprehensive Health	11/15/2018	4337605	Testosterone 80mg	1 pellet	3

Attachment A - Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Horizona Women's Healthcare	4/12/2018	4157188	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191354	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228907	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254954	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295757	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	10/12/2018	4308573	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329584	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618237	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641028	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/5/2016	3671296	Testosterone 50mg	1 pellet	1
Horizona Women's Healthcare	4/28/2016	3686816	Testosterone 50mg	1 pellet	5
Horizona Women's Healthcare	6/14/2016	3711434	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	7/29/2016	3740126	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792880	Testosterone 50mg	1 pellet	5
Horizona Women's Healthcare	11/19/2016	3808773	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	12/29/2016	3832722	Testosterone 50mg	1 pellet	2
Horizona Women's Healthcare	1/24/2017	3848127	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881248	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900231	Testosterone 50mg	1 pellet	3
Horizona Women's Healthcare	7/10/2017	3902995	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/11/2017	3986065	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	10/12/2017	4028466	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	12/13/2017	4075010	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	2/15/2018	4117560	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140346	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/2/2018	4174736	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191355	Testosterone 50mg	1 pellet	4
Horizona Women's Healthcare	7/10/2018	4228995	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254953	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273330	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295758	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/31/2018	4322777	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329583	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618236	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641027	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	4/5/2016	3671297	Testosterone 87.5mg	1 pellet	4
Horizona Women's Healthcare	4/28/2016	3685821	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	6/14/2016	3711432	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	7/29/2016	3740177	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	8/18/2016	3752248	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792879	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3808774	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	1/24/2017	3848128	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881252	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900228	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	6/7/2017	3940390	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/18/2017	3963355	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	9/25/2017	4016256	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/12/2017	4028467	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	2/15/2018	4117558	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140345	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/12/2018	4157187	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	5/23/2018	4191353	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228994	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273336	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329582	Testosterone 87.5mg	1 pellet	6
Women's Comprehensive Health	4/25/2018	4169948	Anastrozole 8mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169947	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174147	Anastrozole 4mg/Testosterone 100mg	1 pellet	8
Women's Comprehensive Health	5/11/2018	4183371	Anastrozole 4mg/Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/6/2018	4202617	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	7/30/2018	4244525	Anastrozole 4mg/Testosterone 100mg	1 pellet	5
Women's Comprehensive Health	8/15/2018	4259698	Anastrozole 4mg/Testosterone 100mg	1 pellet	4
Women's Comprehensive Health	8/23/2018	4265829	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	9/18/2018	4287308	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322779	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	11/15/2018	4337599	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	4/18/2018	4164498	Anastrozole 4mg/Testosterone 60mg	1 pellet	1
Women's Comprehensive Health	6/6/2018	4202555	Anastrozole 4mg/Testosterone 60mg	1 pellet	4
Women's Comprehensive Health	6/18/2018	4212758	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	8/15/2018	4259699	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322780	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	11/15/2018	4337588	Anastrozole 4mg/Testosterone 60mg	1 pellet	2

Attachment A- Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Horizons Women's Healthcare	10/26/2016	3792878	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	11/18/2016	3809770	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	12/29/2016	3832777	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	1/24/2017	3849129	Testosterone 100mg	1 pellet	6
Horizons Women's Healthcare	3/15/2017	3863552	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	3/31/2017	3881247	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	4/11/2017	3900279	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	5/8/2017	3919671	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	6/7/2017	3940358	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	7/10/2017	3962066	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	8/13/2017	3983836	Testosterone 100mg	1 pellet	6
Horizons Women's Healthcare	8/11/2017	3986058	Testosterone 100mg	1 pellet	30
Horizons Women's Healthcare	8/21/2017	3993993	Testosterone 100mg	1 pellet	40
Horizons Women's Healthcare	9/11/2017	4006351	Testosterone 100mg	1 pellet	30
Horizons Women's Healthcare	9/25/2017	4016290	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	10/13/2017	4028458	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	11/1/2017	4043108	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	12/1/2017	4063716	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	12/13/2017	4075098	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	1/30/2018	4092503	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	3/15/2018	4117552	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	3/8/2018	4132332	Testosterone 100mg	1 pellet	6
Horizons Women's Healthcare	3/20/2018	4143390	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	5/12/2018	4157186	Testosterone 100mg	1 pellet	6
Horizons Women's Healthcare	5/1/2018	4174775	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	5/23/2018	4191352	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	6/22/2018	4210843	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	7/10/2018	4228993	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	8/9/2018	4254952	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	8/31/2018	4273329	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	9/26/2018	4294070	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	10/12/2018	4308871	Testosterone 100mg	1 pellet	15
Horizons Women's Healthcare	11/7/2018	4329586	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	11/29/2018	4347878	Testosterone 100mg	1 pellet	15
Horizons Women's Healthcare	3/11/2016	3657079	Testosterone 25mg	1 pellet	4
Horizons Women's Healthcare	4/5/2016	36/1298	Testosterone 25mg	1 pellet	3
Horizons Women's Healthcare	6/14/2016	3711419	Testosterone 25mg	1 pellet	5
Horizons Women's Healthcare	7/29/2016	3740151	Testosterone 25mg	1 pellet	4
Horizons Women's Healthcare	8/19/2016	3752746	Testosterone 25mg	1 pellet	4
Horizons Women's Healthcare	10/3/2016	3778852	Testosterone 25mg	1 pellet	5
Horizons Women's Healthcare	11/16/2016	3803774	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	1/24/2017	3848176	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	3/14/2017	3881283	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	4/11/2017	3900327	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	5/8/2017	3919670	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	7/10/2017	3962094	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	7/18/2017	3968367	Testosterone 25mg	1 pellet	4
Horizons Women's Healthcare	8/11/2017	4006351	Testosterone 25mg	1 pellet	4
Horizons Women's Healthcare	10/12/2017	4028461	Testosterone 25mg	1 pellet	10
Horizons Women's Healthcare	12/13/2017	4073014	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	2/6/2018	4109018	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	3/20/2018	4143381	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	4/12/2018	4157190	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	5/2/2018	4174775	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	5/23/2018	4191442	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	7/10/2018	4228996	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	10/12/2018	4308870	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	10/31/2018	4332773	Testosterone 25mg	1 pellet	6
Horizons Women's Healthcare	1/12/2016	3619238	Testosterone 37.5mg	1 pellet	3
Horizons Women's Healthcare	2/16/2016	3641039	Testosterone 37.5mg	1 pellet	3
Horizons Women's Healthcare	4/29/2016	3695539	Testosterone 37.5mg	1 pellet	3
Horizons Women's Healthcare	6/14/2016	3711435	Testosterone 37.5mg	1 pellet	3
Horizons Women's Healthcare	8/19/2016	3752247	Testosterone 37.5mg	1 pellet	6
Horizons Women's Healthcare	11/18/2016	3809772	Testosterone 37.5mg	1 pellet	5
Horizons Women's Healthcare	12/29/2016	3832724	Testosterone 37.5mg	1 pellet	7
Horizons Women's Healthcare	2/15/2017	3863550	Testosterone 37.5mg	1 pellet	6
Horizons Women's Healthcare	3/14/2017	3881250	Testosterone 37.5mg	1 pellet	6
Horizons Women's Healthcare	6/7/2017	3940392	Testosterone 37.5mg	1 pellet	6
Horizons Women's Healthcare	7/10/2017	3962097	Testosterone 37.5mg	1 pellet	8
Horizons Women's Healthcare	8/11/2017	3986063	Testosterone 37.5mg	1 pellet	10
Horizons Women's Healthcare	10/12/2017	4028465	Testosterone 37.5mg	1 pellet	10
Horizons Women's Healthcare	12/13/2017	4075099	Testosterone 37.5mg	1 pellet	6
Horizons Women's Healthcare	3/8/2018	4132323	Testosterone 37.5mg	1 pellet	6

Attachment A - Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Body Shapes Medical-Cincinnati	6/6/2017	4002002	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/6/2017	4002004	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/8/2017	4005850	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/23/2017	4015219	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/6/2017	4025569	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/12/2017	4029489	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/1/2017	4043086	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/1/2017	4065305	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/30/2016	3757886	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	10/10/2016	3787518	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	12/15/2016	3825451	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	3/6/2017	3876104	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	6/2/2017	3959646	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	9/18/2016	3660574	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	5/23/2016	3699311	Testosterone cypionate 200mg/ml	30ml	1
Body Shapes Medical-Cincinnati	6/22/2016	3717347	Testosterone cypionate 200mg/ml	30ml	1
Horizons Women's Healthcare	1/15/2016	3621406	Testosterone 200mg	1 pellet	3
Horizons Women's Healthcare	2/9/2016	3636450	Testosterone 200mg	1 pellet	19
Horizons Women's Healthcare	3/18/2016	3643113	Testosterone 200mg	1 pellet	9
Horizons Women's Healthcare	7/22/2016	3684151	Testosterone 200mg	1 pellet	7
Horizons Women's Healthcare	3/11/2016	3657077	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	4/1/2016	3668462	Testosterone 200mg	1 pellet	7
Horizons Women's Healthcare	5/23/2016	3699464	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	6/14/2016	3711440	Testosterone 200mg	1 pellet	6
Horizons Women's Healthcare	7/15/2016	3736487	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	8/19/2016	3752249	Testosterone 200mg	1 pellet	22
Horizons Women's Healthcare	8/12/2016	3764571	Testosterone 200mg	1 pellet	9
Horizons Women's Healthcare	9/15/2016	3787181	Testosterone 200mg	1 pellet	22
Horizons Women's Healthcare	10/3/2016	3778607	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	10/14/2016	3783934	Testosterone 200mg	1 pellet	16
Horizons Women's Healthcare	11/3/2016	3798493	Testosterone 200mg	1 pellet	5
Horizons Women's Healthcare	11/16/2016	3808772	Testosterone 200mg	1 pellet	18
Horizons Women's Healthcare	12/29/2016	3832729	Testosterone 200mg	1 pellet	13
Horizons Women's Healthcare	2/15/2017	3863553	Testosterone 200mg	1 pellet	8
Horizons Women's Healthcare	4/28/2017	3913378	Testosterone 200mg	1 pellet	12
Horizons Women's Healthcare	5/8/2017	3919868	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	5/23/2017	3930920	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	6/22/2017	3937477	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	7/27/2017	3977020	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	10/12/2017	4028469	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	11/1/2017	4051486	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	12/1/2017	4063510	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	12/6/2017	4068168	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	1/12/2018	4092505	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	1/26/2018	4103101	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	2/5/2018	4109021	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	2/20/2018	4120203	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	3/8/2018	4132329	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	6/6/2018	4155895	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	6/14/2018	4209451	Testosterone 200mg	1 pellet	26
Horizons Women's Healthcare	6/22/2018	4216844	Testosterone 200mg	1 pellet	6
Horizons Women's Healthcare	7/10/2018	4229002	Testosterone 200mg	1 pellet	12
Horizons Women's Healthcare	7/10/2018	4230133	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	7/25/2018	4242799	Testosterone 200mg	1 pellet	30
Horizons Women's Healthcare	8/20/2018	4263218	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	7/28/2018	4269213	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	8/31/2018	4273332	Testosterone 200mg	1 pellet	10
Horizons Women's Healthcare	8/26/2018	4294081	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	9/26/2018	4285756	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	10/31/2018	4322776	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	11/7/2018	4329581	Testosterone 200mg	1 pellet	15
Horizons Women's Healthcare	11/29/2018	4347677	Testosterone 200mg	1 pellet	20
Horizons Women's Healthcare	1/12/2016	3618235	Testosterone 100mg	1 pellet	8
Horizons Women's Healthcare	2/16/2016	3641026	Testosterone 100mg	1 pellet	8
Horizons Women's Healthcare	3/11/2016	3657078	Testosterone 100mg	1 pellet	8
Horizons Women's Healthcare	4/5/2016	3671285	Testosterone 100mg	1 pellet	9
Horizons Women's Healthcare	4/28/2016	3685827	Testosterone 100mg	1 pellet	8
Horizons Women's Healthcare	5/23/2016	3699465	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	6/14/2016	3711435	Testosterone 100mg	1 pellet	5
Horizons Women's Healthcare	6/28/2016	3721136	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	7/29/2016	3740175	Testosterone 100mg	1 pellet	10
Horizons Women's Healthcare	8/19/2016	3752242	Testosterone 100mg	1 pellet	15
Horizons Women's Healthcare	10/3/2016	3778601	Testosterone 100mg	1 pellet	10

Attachment A - Sales made by AzuzaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Body Shapes Medical-Cincinnati	6/21/2017	3951911	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/26/2017	3953647	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/14/2017	3966321	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/14/2017	3966324	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/17/2017	3967192	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/27/2017	3975585	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/2/2017	3979290	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983032	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983035	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/14/2017	3987378	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/15/2017	3987893	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/25/2017	3995202	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/29/2017	3997370	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/6/2017	4002143	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/8/2017	4002146	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/8/2017	4003443	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/19/2017	4011908	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/6/2017	4025553	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/9/2017	4026999	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/12/2017	4029488	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/25/2017	4038722	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/1/2017	4043085	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/7/2017	4047308	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/10/2017	4050342	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/14/2017	4053294	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2017	4053766	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2017	4054737	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2017	4054741	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/1/2017	4065303	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/1/2017	4068069	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/11/2017	4074415	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/12/2017	4072352	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2016	3650499	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660864	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3660867	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3667353	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3668070	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/23/2016	3698593	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2016	3702969	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/20/2016	3714866	Testosterone 37.5mg	1 pellet	2
Body Shapes Medical-Cincinnati	6/29/2016	3721099	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/30/2016	3722257	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/6/2016	3731293	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767063	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767083	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767071	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2016	3805328	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807134	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807138	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826945	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826909	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/18/2017	3845980	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/10/2017	3866110	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2017	3878058	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/9/2017	3878143	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/28/2017	3891091	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903165	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/24/2017	3909529	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/1/2017	3914204	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/3/2017	3916900	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/15/2017	3925278	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2017	3935457	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3936672	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3937160	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946359	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946398	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/26/2017	3953966	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/2/2017	3979291	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983036	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/8/2017	3983036	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/14/2017	3987329	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/25/2017	3995703	Testosterone 37.5mg	1 pellet	1
Body Shapes Medical-Cincinnati	8/29/2017	3997368	Testosterone 37.5mg	1 pellet	1

Attachment A - Sales made by Anapain Health Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Advanced Pain and Spine Inst	6/6/2018	4203383	Testosterone 200mg	1 pellet	17
Advanced Pain and Spine Inst	8/30/2018	4272793	Testosterone 200mg	1 pellet	8
Advanced Pain and Spine Inst	6/6/2018	4203382	Testosterone 100mg	1 pellet	23
Advanced Pain and Spine Inst	6/26/2018	4218767	Testosterone 100mg	1 pellet	6
Advanced Pain and Spine Inst	7/20/2018	4238671	Testosterone 100mg	1 pellet	20
Advanced Pain and Spine Inst	7/26/2018	4243189	Testosterone 100mg	1 pellet	5
Advanced Pain and Spine Inst	8/30/2018	4272798	Testosterone 100mg	1 pellet	30
Advanced Pain and Spine Inst	6/6/2018	4203379	Testosterone 25mg	1 pellet	2
Advanced Pain and Spine Inst	6/20/2018	4214066	Testosterone 25mg	1 pellet	3
Advanced Pain and Spine Inst	6/26/2018	4218764	Testosterone 25mg	1 pellet	3
Advanced Pain and Spine Inst	7/20/2018	4238674	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst	7/26/2018	4243188	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst	8/30/2018	4272795	Testosterone 25mg	1 pellet	5
Advanced Pain and Spine Inst	6/6/2018	4203380	Testosterone 50mg	1 pellet	1
Advanced Pain and Spine Inst	6/26/2018	4218765	Testosterone 50mg	1 pellet	2
Advanced Pain and Spine Inst	7/20/2018	4238675	Testosterone 50mg	1 pellet	5
Advanced Pain and Spine Inst	8/30/2018	4272796	Testosterone 50mg	1 pellet	2
Advanced Pain and Spine Inst	6/6/2018	4203381	Testosterone 80mg	1 pellet	1
Advanced Pain and Spine Inst	6/26/2018	4218766	Testosterone 80mg	1 pellet	2
Advanced Pain and Spine Inst	7/20/2018	4238676	Testosterone 80mg	1 pellet	5
Advanced Pain and Spine Inst	8/30/2018	4272797	Testosterone 80mg	1 pellet	5
Body Shapes Medical-Cincinnati	1/26/2016	3629652	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	3/7/2016	3650501	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3669063	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/18/2016	3669066	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3667354	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3686072	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/31/2016	3685075	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/23/2016	3698594	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2016	3702871	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/20/2016	3714865	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/29/2016	3721012	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/30/2016	3722277	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/6/2016	3724903	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	7/7/2016	3725539	Testosterone 100mg	1 pellet	16
Body Shapes Medical-Cincinnati	9/15/2016	3767058	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	9/15/2016	3767063	Testosterone 100mg	1 pellet	3
Body Shapes Medical-Cincinnati	9/29/2016	3775519	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	10/17/2016	3786327	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	11/9/2016	3801491	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/15/2016	3805327	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/16/2016	3806305	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807123	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	11/17/2016	3807137	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826904	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826907	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	12/19/2016	3826911	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/6/2017	3838382	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/18/2017	3845957	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	1/30/2017	3852887	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/6/2017	3857337	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	2/10/2017	3861106	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/2/2017	3873979	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/6/2017	3876304	Testosterone 100mg	1 pellet	14
Body Shapes Medical-Cincinnati	3/9/2017	3878541	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/9/2017	3878543	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	3/28/2017	3891090	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903187	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/14/2017	3903190	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/24/2017	3909586	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/27/2017	3912100	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	4/28/2017	3913656	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/1/2017	3914206	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/3/2017	3916899	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/9/2017	3921007	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/15/2017	3925279	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/24/2017	3931243	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	5/31/2017	3935009	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3936871	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/1/2017	3937183	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/5/2017	3938563	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946391	Testosterone 100mg	1 pellet	1
Body Shapes Medical-Cincinnati	6/15/2017	3946397	Testosterone 100mg	1 pellet	1

Attachment A - Sales made by Anazaohealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Women's Comprehensive Health	6/6/2018	4202556	Anastrozole 4mg/Testosterone 75mg	1 pellet	1
Women's Comprehensive Health	4/19/2018	4164499	Anastrozole 8mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	4/18/2018	4164501	Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169946	Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	5/1/2018	4174148	Testosterone 100mg	1 pellet	12
Women's Comprehensive Health	5/11/2018	4183229	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212752	Testosterone 100mg	1 pellet	6
Women's Comprehensive Health	6/25/2018	4217896	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	7/17/2018	4236811	Testosterone 100mg	1 pellet	15
Women's Comprehensive Health	7/30/2018	4244570	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/15/2018	4259700	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265837	Testosterone 100mg	1 pellet	20
Women's Comprehensive Health	9/14/2018	4287286	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299217	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322428	Testosterone 100mg	1 pellet	12
Women's Comprehensive Health	11/15/2018	4337609	Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/25/2018	4217897	Testosterone 12.5mg	1 pellet	3
Women's Comprehensive Health	7/30/2018	4244521	Testosterone 12.5mg	1 pellet	9
Women's Comprehensive Health	10/29/2018	4322441	Testosterone 12.5mg	1 pellet	2
W[redacted]...prehensive Health	6/25/2018	4217895	Testosterone 25mg	1 pellet	2
Women's Comprehensive Health	7/17/2018	4236814	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	7/30/2018	4244527	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	8/23/2018	4265832	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	9/18/2018	4297309	Testosterone 25mg	1 pellet	5
Women's Comprehensive Health	10/2/2018	4299218	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322427	Testosterone 25mg	1 pellet	8
Women's Comprehensive Health	11/15/2018	4337607	Testosterone 25mg	1 pellet	10
Women's Comprehensive Health	6/18/2018	4212752	Testosterone 37.5mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236816	Testosterone 37.5mg	1 pellet	5
Women's Comprehensive Health	7/30/2018	4244523	Testosterone 37.5mg	1 pellet	5
Women's Comprehensive Health	10/29/2018	4322439	Testosterone 37.5mg	1 pellet	3
Women's Comprehensive Health	6/18/2018	4212754	Testosterone 50mg	1 pellet	1
Women's Comprehensive Health	7/17/2018	4236818	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	7/30/2018	4244524	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	8/23/2018	4265834	Testosterone 50mg	1 pellet	8
Women's Comprehensive Health	9/18/2018	4297307	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/2/2018	4299220	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	10/29/2018	4322428	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	11/15/2018	4337604	Testosterone 50mg	1 pellet	10
Women's Comprehensive Health	4/25/2018	4169945	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174149	Testosterone 80mg	1 pellet	2
Women's Comprehensive Health	5/11/2018	4183269	Testosterone 80mg	1 pellet	7
Women's Comprehensive Health	6/18/2018	4212756	Testosterone 80mg	1 pellet	3
Women's Comprehensive Health	7/17/2018	4236819	Testosterone 80mg	1 pellet	4
Women's Comprehensive Health	8/23/2018	4265831	Testosterone 80mg	1 pellet	1
Women's Comprehensive Health	10/2/2018	4299219	Testosterone 80mg	1 pellet	3
Women's Comprehensive Health	10/29/2018	4322429	Testosterone 80mg	1 pellet	5
Women's Comprehensive Health	11/15/2018	4337603	Testosterone 80mg	1 pellet	5

Attachment A- Sales made by AnazaoHealth Corporation

Facility Name	Date	Invoice Number	Medication	Package Size	Quantity
Horizona Women's Healthcare	4/12/2018	4157198	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191354	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228997	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254954	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295752	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	10/12/2018	4308873	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329564	Testosterone 37.5mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618337	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641028	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/5/2016	3671296	Testosterone 50mg	1 pellet	1
Horizona Women's Healthcare	4/28/2016	3685816	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	6/14/2016	3711434	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	7/29/2016	3740126	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792880	Testosterone 50mg	1 pellet	5
Horizona Women's Healthcare	11/18/2016	3808773	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	12/29/2016	3832722	Testosterone 50mg	1 pellet	2
Horizona Women's Healthcare	1/24/2017	3848127	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881248	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900231	Testosterone 50mg	1 pellet	3
Horizona Women's Healthcare	7/10/2017	3962095	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/11/2017	3986065	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	10/13/2017	4028466	Testosterone 50mg	1 pellet	10
Horizona Women's Healthcare	12/13/2017	4075010	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	7/15/2018	4117560	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140346	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/2/2018	4174726	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	5/23/2018	4191355	Testosterone 50mg	1 pellet	4
Horizona Women's Healthcare	7/10/2018	4228995	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/9/2018	4254953	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273330	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	9/26/2018	4295758	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	10/31/2018	4322777	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329583	Testosterone 50mg	1 pellet	6
Horizona Women's Healthcare	1/12/2016	3618236	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	2/16/2016	3641027	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	4/5/2016	3671297	Testosterone 87.5mg	1 pellet	4
Horizona Women's Healthcare	4/28/2016	3685823	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	6/14/2016	3711432	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	7/29/2016	3740177	Testosterone 87.5mg	1 pellet	3
Horizona Women's Healthcare	8/19/2016	3752248	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/26/2016	3792879	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/18/2016	3808774	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	1/24/2017	3848128	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/14/2017	3881252	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/11/2017	3900228	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	6/7/2017	3940390	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/13/2017	3968365	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	9/25/2017	4016256	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	10/13/2017	4028467	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/15/2018	4117558	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	3/20/2018	4140345	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	4/12/2018	4157187	Testosterone 87.5mg	1 pellet	5
Horizona Women's Healthcare	5/23/2018	4191353	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	7/10/2018	4228994	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	8/31/2018	4273336	Testosterone 87.5mg	1 pellet	6
Horizona Women's Healthcare	11/7/2018	4329582	Testosterone 87.5mg	1 pellet	6
Women's Comprehensive Health	4/5/2018	4169948	Anastrozole 8mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	4/25/2018	4169947	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	5/1/2018	4174147	Anastrozole 4mg/Testosterone 100mg	1 pellet	9
Women's Comprehensive Health	5/11/2018	4183271	Anastrozole 4mg/Testosterone 100mg	1 pellet	10
Women's Comprehensive Health	6/6/2018	4202617	Anastrozole 4mg/Testosterone 100mg	1 pellet	1
Women's Comprehensive Health	7/30/2018	4244525	Anastrozole 4mg/Testosterone 100mg	1 pellet	5
Women's Comprehensive Health	8/15/2018	4259698	Anastrozole 4mg/Testosterone 100mg	1 pellet	4
Women's Comprehensive Health	8/23/2018	4265829	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	9/18/2018	4287308	Anastrozole 4mg/Testosterone 100mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322779	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	11/15/2018	4337599	Anastrozole 4mg/Testosterone 100mg	1 pellet	3
Women's Comprehensive Health	4/18/2018	4164498	Anastrozole 4mg/Testosterone 60mg	1 pellet	1
Women's Comprehensive Health	6/6/2018	4202555	Anastrozole 4mg/Testosterone 60mg	1 pellet	4
Women's Comprehensive Health	6/18/2018	4212758	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	8/15/2018	4259699	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	10/29/2018	4322780	Anastrozole 4mg/Testosterone 60mg	1 pellet	2
Women's Comprehensive Health	11/15/2018	4337588	Anastrozole 4mg/Testosterone 60mg	1 pellet	2

Eric Sparks, on behalf of, AnazaoHealth Corporation, Respondent	Date of Signature
Attorney for Respondent (if applicable)	Date of Signature
Jennifer M. Rudell, RPh, President, State of Ohio Board of Pharmacy	Date of Signature
Henry G. Appel, Ohio Assistant Attorney General	Date of Signature

9. AnazaoHealth Corporation waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. AnazaoHealth Corporation neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 25, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. AnazaoHealth Corporation agrees to pay to the Board a monetary penalty in the amount of $2,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. AnazaoHealth Corporation agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. AnazaoHealth Corporation agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by AnazaoHealth Corporation of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to AnazaoHealth Corporation by the Board and will NOT discharge AnazaoHealth Corporation from any obligation under the terms of this Agreement.

6. AnazaoHealth Corporation agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. AnazaoHealth Corporation understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom AnazaoHealth Corporation will operate.

BY ORDER OF THE STATE BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/jak/pae

CMRRR: 7020 3160 0000 6109 0748

Enclosure: Attachment A

a. Violating any federal, state, or local drug law; any provision of chapter 4729. or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2)(b); and/or

b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(2)(d); and/or

c. Any other cause for which the board may impose sanctions as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.56(A)(2)(g).

6. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2015, each violation punishable by a maximum fine of $2,500 if committed by an organization:

   a. Violating any federal, state, or local drug law; any provision of this chapter or Chapter 2925., 3715., or 3719. of the Revised Code; or any rule of the Board, ORC Section 4729.56(A)(2); and/or

   b. Failing to satisfy the qualifications for registration under section 4729.53 of the Revised Code or the rules of the Board or ceasing to satisfy the qualifications after the registration is granted or renewed, ORC Section 4729.56(A)(4).

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, each violation punishable by a maximum penalty of $2,500: Is not of good moral character and habits.

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

b. Advanced Pain and Spine Institute, no TDDD license, located at 9600 Montgomery Road, Cincinnati, Ohio.

c. Body Shapes Medical-Cincinnati, only a Category II TDDD license, located at 11147 Montgomery Road, Suite 200, Cincinnati, Ohio.

d. Women's Comprehensive Health Center, no TDDD license, located at 135 N. Ewing Street, Suite 205, Lancaster, Ohio.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, as effective September 29, 2017, no wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following: Subject to division (D) of this section, a licensed terminal distributor of dangerous drugs, each sale being a first-degree misdemeanor, each punishable by a maximum fine of $5,000 if committed by an organization.

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A)(1) of the ORC, as effective April 6, 2017, September 29, 2017, Before a licensee identified in division (B)(1)(a) of section 4729.52 of the Revised Code may sell or distribute dangerous drugs at wholesale to any person, except as provided in division (A)(2) of this section, the licensee shall query the roster established pursuant to section 4729.59 of the Revised Code to determine whether the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(A) of the ORC, as effective April 21, 2014 and February 1, 2016, Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1)(a) to (d), (f) to (h), and (l) to (p) of section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of $2,500 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Rule 4729-9-12(A)(1) of the OAC, as effective October 5, 2015, Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the Board's online registry to confirm licensure, each punishable by a maximum fine of $2,500 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes the following violations of Section 4729.56 of the ORC, effective September 29, 2017, each violation punishable by a maximum fine of $2,500 if committed by an organization:

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Home Infusion/Specialty	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Home Infusion/Specialty

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Oakstead Infusion Vital Care

Physical Address: 1492 W Antelope Dr, Suite 208

City: Layton State: UT Zip: 84041

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 801-825-3879 Toll Free # (NAC 639.708, NRS 639.23286): 888-285-5879

Fax: 801-991-6924 Contact Email: tswakefield@vitalcare.com

Website: www.oaksteadinfusion.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Trent Wakefield

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 16417

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.232B. (Use a separate piece of paper if additional space is needed.)

Name: Trent Wakefield	NV Pharmacist Registration #: 16417
Name: Marianne Tyson	NV Pharmacist Registration #: 21350
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): N/A

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): N/A

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: N/A

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Robert Galeria

Business Name: Oakstead Infusion Pharmacy LLC

Business Address: 1492 W Antelope Dr, Suite 208

City: Layton State: UT Zip: 84041

Telephone: 801-825-3879 Email: rpgaleria@vitalcare.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Oakstead Infusion Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert Galeria

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/30/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Trent Wakefield

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/30/24
Date

Board Use Only	Date Received: 1/8/25	Amount: $500 CK 0463023016

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

MARGARET W. BUSSE
Executive Director

MARK B. STEINAGEL
Division Director

VERIFICATION OF UTAH LICENSURE

DOPL-FM-001 REV 06/08/2009
Created On: 12/3/2024
Created By: Henele Tupou

Name of Licensee (as it appears in our records): Oakstead Infusion Pharmacy, LLC. DBA: Oakstead Infusion Vital Care

Classification of License Issued: Pharmacy - Class B
Dispensing Controlled Substance License

License Number: 9704028-1704
9704028-8913

Obtained by: Application

Current Status: Active

Original Date of Licensure: 03/03/2016

Expiration Date: 09/30/2025

No Disciplinary Action.

Signature: _____ Date: December 3, 2024

Henele Tupou
Licensing Specialist
801-530-6628
htupou@utah.gov

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. If you have any questions, please contact the division.

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

Oakstead Infusion Pharmacy, LLC.
DBA: Oakstead Infusion Vital Care

EFFECTIVE
03/03/2016

EXPIRATION
09/30/2025

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

9704028-1704 Pharmacy - Class B
9704028-8913 Dispensing Controlled Substance License
Closed Door

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

OAKSTEAD INFUSION PHARMACY, LLC. DBA:
OAKSTEAD INFUSION VITAL CARE
1492 W ANTELOPE DR STE 208
LAYTON UT 84041

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: 03/03/2016
EXPIRATION DATE: 09/30/2025
ISSUED TO: Oakstead Infusion Pharmacy, LLC. DBA:
Oakstead Infusion Vital Care
1492 W ANTELOPE DR STE 208
LAYTON UT 84041

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)
9704028-1704 Pharmacy - Class B Closed Door
9704028-8913 Dispensing Controlled Substance License
DBAs: None Associated

Form #1

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO5904556	12-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-04-2024

OAKSTEAD INFUSION PHARMACY, LLC
DBA: OAKSTEAD INFUSION VITAL CARE
1492 W ANTELOPE DR STE 208
LAYTON, UT 840411158

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO5904556	12-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-04-2024

OAKSTEAD INFUSION PHARMACY, LLC
DBA: OAKSTEAD INFUSION VITAL CARE
1492 W ANTELOPE DR STE 208
LAYTON, UT 840411158

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Oakstead Infusion Vital Care

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1492 W Antelope Dr, Suite 208

City: Layton State: UT Zip: 84041

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 801-825-3879 Toll Free # (NAC 639.708, NRS 639.23286): 888-285-5879

Fax: 801-991-6924 Contact Email: tswakefield@vitalcare.com

Website: www.oaksteadinfusion.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Trent Wakefield

Supervising/Managing Pharmacist NV Pharmacist Registration #: 16417

Name of Designated Person(s) as defined by revised USP-797 guidelines: Trent Wakefield

Email of Designated Person(s): tswakefield@vitalcare.com

Telephone of Designated Person(s): 801-825-3879, 702-278-1284

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 09/24/2024

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☐ Yes ■ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? once monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

IV antibiotics:
Vancomycin, Daptomycin, Cefazolin, Ceftriaxone, Cefepime, Ertapenem, Meropenem, Zosyn, Penicillins (Pen G, Nafcillin), Teflaro, Tygacil, etc.

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of compounded products include pharmacist review or compounding record to make sure drug, lot #'s, and compounding instructions are accurate before entry into the clean room. Compounding is observed by a pharmacy from outside of the clean room. Once compounded product is complete it is removed from the clean room and inspected by a pharmacist for measureing accuracy and particulate matter with black and white background. Once accuracy is determined it is inspected prior to packaging for shipment/delivery.

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months for all pharmacists and technicians who compound or check compounded products.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Upon hire all pharmacists and pharmacy technician complete Vitalcare's sterile compounding didactic training. It includes: Initial 3 time fingertip testing and media fill (including surface sample), Cleaning and Disinfection of The Controlled Air Environments, Monthly Cleaning with Sporicidal agent, Surface Sampling, Proper Gloving/Gowning Procedure and Entry Into the Clean Room, Preparation of the Aseptic Work Environment, Reconstitution and Aseptic Transfer of a Solution from a Vial to Final container, Aspetic transfer of a solution from vial to a syringe, Aspetic transer of a solution from a ampule to syringe, Aseptic Processing of Compounded Sterile Preparations, Aseptic transfer of solution and medication to an elastomeric, Use of automated and assistive devices during sterile compounding procedures.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Daily PEC: surfaces of inside area of the LAFW and all class 5 areas of clean bench will be disinfected daily using Sterile TB1-3300, and then sanitized with Sterile IPA 70%. Done prior to starting the compounding shift for the day. To ensure no bacteria or fungus is in the class 5 areas, Sterile TB1-3300 will be left on the surface for 1 minute before sanitizing with Sterile IPA 70%. 8. Additionally, ISO Class 5 critical work areas will be sanitized with sterile 70% IPA between prescription compounding, and every 30 minutes while the room is being used, after spills and if contamination is suspected.
Daily Cleaning of SEC/Clean room and Ante room: Mop floors and surfaces in pass through with PreEmpt Plus RTU starting at the (cleanest point) farthest point from the entrance working toward the ante-area. All mop heads and handles will be sanitized with Sterile IPA 70% or PreEmpt Plus RTU immediately prior to use. Clean the tops of all counters, carts, stools, surfaces in pass-through compartments and any other easily cleanable work surfaces with PreEmpt Plus RTU, let dwell 1 minute, then sanitize with Sterile IPA. ANTE-AREA/ROOM (CLEANED AFTER THE COMPOUNDING/BUFFER ROOM) using PreEmpt Plus RTU to disinfect the sink, tops of all counters, carts, stools, and any other easily cleanable work surfaces.
Monthly Cleaning of Controlled Environments: The class 5 areas will be treated with Sterile Peridox RTU, with a dwell time of 3 minutes to achieve maximum disinfection and sporicidal activity. Sterile Peridox RTU will be removed from metal components with sterile water, then sanitize with sterile IPA 70% after the water rinse.

17. Who performs the sterile compounding process at your facility?

Compounding technicians and pharmacists for on call needs.

18. Who is responsible and accountable for the sterile compounding process at your facility?
Trent Wakefield, PharmD (PIC/Pharmacy Manager), Nick Kemp, PharmD serves as backup responsible person in the absense of the PIC.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
We use Kodiakooler shipping containers to ensure product safety, efficacy and proper temperature stability.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TRENT WAKEFIELD

Name of Person who Completed the Form

PHARMACY MANAGER / PIC

Title

Signature (copies or stamps not accepted)

12/30/2024

Date

Board Use Only	Date Received: 1/8/25	Date Approved: _____	Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Oakstead Infusion Vital Care

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1492 W Antelope Dr, Suite 208

City: Layton State: UT Zip: 84041

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 801-825-3879 Website: www.oaksteadinfusion.com

Licensing Company Email: tswakefield@vitalcare.com

Section 2: Personal Information

First: Trent Middle: Stilson Last: Wakefield

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Herriman State: UT Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Emery High School		Castle Dale	UT		08/1993 - 05/1995	High School Diploma
College Of Eastern Utah		Price	UT		08/1995 - 05/1996	
Utah State University		Vernal	UT		08/1997 - 05/1998	
Utah Valley University		Orem	UT		08/1998 - 05/2000	Associates Degree
Roseman University	11 Sunset Way	Henderson	NV	89014	08/2000 - 06/2004	PharmD

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/2020 - Present	[redacted]	Herriman	UT	[redacted]
06/18 - 07/20		Herriman	UT	
08/15 - 06/18		South Jordan	UT	
12/14 - 08/15		Orangeville	UT	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Oakstead Infusion Vital Care			09/24 - Current
Business Address	**City**	**State**	**Zip**
1492 W Antelope Dr, Suite 208	Layton	UT	84041
Phone	**Title**		**Number of Employed Hours**
801-825-3879	Pharmacy Manager / PIC		640
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Amerita Specialty Infusion			08/16 - 09/24
Business Address	**City**	**State**	**Zip**
2446 S Progress Dr	Salt Lake City	UT	84119
Phone	**Title**		**Number of Employed Hours**
801-908-6100	Pharmacy Manager / General Manager		19,200
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Trent Wakefield, **certify that as the designated representative for**

Oakstead Infusion Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TW I am at least 21 years of age;
3. TW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Trent Wakefield

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Trent Wakefield

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/30/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Trent Wakefield, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/30/2024

Date

Subscribed and Sworn to before me this 30th day of December.

Notary Public Signature

ALEXIS SOUTHARD
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 733426
COMM. EXP. 09/29/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Oakstead Infusion Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 9704028-1704

Physical Address: 1492 W Antelope Dr 208

City: Layton State: UT Zip: 84041

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 801-825-3879 Website: oaksteadinfusion.com

Licensing Company Email: rpgaleria@vitalcare.com

Section 2: Personal Information

First: Robert Middle: Paul Last: Galeria

Alias(es, nicknames, name changes, etc.): Robby

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Kaysville State: UT Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Thousand Oaks High School		09/1998-06/2002	
Address	**City**	**State**	**Zip**
2323 N Moorpark Rd	Thousand Oaks	CA	91360
Diploma/Degree obtained, if any			
Graduated High School			

School Name		From - To (MM/YY – MM/YY)	
BYU-Idaho		09/2002-12/2010	
Address	**City**	**State**	**Zip**
525 S Center St	Rexburg	ID	83460
Diploma/Degree obtained, if any			
Bachelors - Business			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2021-Present	[redacted]	Kaysville	UT	[redacted]
05/2015-06/2021		Kaysville	UT	
11/2011-05/2015		Salt Lake	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Oakstead Infusion Pharmacy LLC			11/2015-Present
Business Address	**City**	**State**	**Zip**
1492 W Antelope Dr 208	Layton	UT	84041
Phone	**Title**		
801-825-3879	Manager		
Description of Duties			
Manager/ Owner			

Business Name			From - To (MM/YY – MM/YY)
Guardian Life Insurance			11/2011-Present
Business Address	**City**	**State**	**Zip**
1484 Thoroughbred Dr	Kaysville	UT	84037
Phone	**Title**		
805-630-2072	Financial Representative		
Description of Duties			
Sell insurance investment products.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Galeria

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/30/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Davis

I, Robert Galeria, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/30/24

Date

Subscribed and Sworn to before me this 30 day of Dec 2024.

Bailey Thomas

Notary Public Signature

BAILEY THOMAS
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 723054
COMM. EXP. 03/13/2026

(Seal)

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741
Email: DOPLInvestigations@utah.gov
Telephone : (801) 530-6628
Toll Free in Utah: (866) 275-3675
Investigation Fax: (801) 530-6301
Website: www.dopl.utah.gov

CLASS B
CLOSED DOOR
INSPECTION

☑ Random
☐ Opening

INFORMATION

Pharmacy Name: Oakstead Infusion Pharmacy, LLC; DBA: Oakstead Infusion Vital Care Date: 7-6-2022

License Number: 9704028-1704 Exp Date: 09/30/2023

C.S. License Number: 9704028-8913 Exp Date: 09/30/2023

DEA Registration: F05904556 Exp Date: 12-31-2024

Pharmacy FEIN #: 47-5399800

Pharmacy Email: argaleria@vitalcareinc.com

Pharmacy Phone: 801-825-3879 Fax: 801-991-6924

Toll Free Number: 888-285-5879

Affiliated Websites: www.oakstedinfusion.com

Pharmacy Hours: Monday-Friday: 8-5:30 Saturday: on call Sunday: on call

Pharmacy Address: 1492 W Antelope Dr Ste 208

City: Layton State: UT Zip: 84041

Pharmacist in Charge (PIC): Aleesha Richman Galeria

PIC License #: 6537899-1701 Expiration Date: 09/30/2023

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name:	License #	Exp:
	See list	

Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

INSPECTION

	YES	NO	
1	✓		Class B pharmacy means a pharmacy located in Utah that is authorized to provide pharmaceutical care for patients in an institutional setting; and whose primary purpose is to provide a physical environment for patients to obtain health care services; and includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and pharmaceutical administration and sterile product preparation facilities. [UCA 58-17b-102 (11)(a)(i-ii)(b)(i-ii)]
2	✓		The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)]
3	✓		Notification has been provided to the Division in regards to the unique email address used in self audits or alerts for the pharmacy. The pharmacy will notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603(3)(t) (i-ii)]
4	✓		Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
5			If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ✓ N/A
6	✓		A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist. [UAC R156-17b-601(4)(a)]
7	✓		Pharmacy technicians shall have general supervision by a pharmacist. [UCA 58-17b-102 (56)]
8	✓		The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(1)(d)(i)]
9			In accordance with Subsecton 58-17b-102(71)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)] N/A
10			In accordance with Subsection 58-17b-102(71)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including: stock ordering and restocking; cashiering; billing; filing; receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee; housekeeping; and delivering a pre-filled prescription to a patient. [UAC R156-17b-607 (1)(a-g)] N/A

11 ☑ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

12 ☑ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

13 ☑ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

14 ☑ ☐ The facility or parent company does maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

15 ☑ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]

- ☑ UCA 58-1 (DOPL Licensing Act)
- ☑ UAC R156-1 (General Rules of DOPL)
- ☑ UCA 58-17b (Pharmacy Practice Act)
- ☑ UAC R156-17b (Pharmacy Practice Act Rules)
- ☑ UCA 58-37 (Controlled Substance Act)
- ☑ UAC R156-37 (Controlled Substance Act Rules)
- ☑ UCA 58-37f (Controlled Substance Database Act)
- ☑ UAC R156-37f (Controlled Substance Database Act Rule)
- ☑ Code of Federal Regulations Title 21 parts 1300 to end
- ☑ FDA Approved Drug Product (Orange Book)
- ☑ General Drug References

16 ☑ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

17 ☑ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1) (b)]

18 ☑ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (c)]

19 ☑ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (d)]

20 ☑ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605 (1)]

21 ☑ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (e)]

22 ☑ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1) (f)(i-ii)(g)]

23 ☑ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] ☐ N/A

24 ☑ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]

25 ☑ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156-17b-614a(6)]

26 ☑ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (2)]

27 ☑ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log entry for three years. [UAC R156-17b-614a (2)]

28 ☑ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☑ Inappropriate drug utilization
- ☑ Therapeutic duplications
- ☑ Drug-disease contraindications
- ☑ Drug-drug interactions
- ☑ Incorrect drug dosage
- ☑ Incorrect duration of drug treatment
- ☑ Drug-allergy interactions
- ☑ Clinical abuse or misuse

29 ☑ ☐ Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs. [R156-17b-610 (7)]

30 n/a ☐ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

31 ☑ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

32 ☐ ☑ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

☑ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing:
(a) the name and description of the prescription drug;
(b) the dosage form, dose, route of administration and duration of drug therapy;
(c) intended use of the drug, when known, and expected action;
(d) special directions and precautions for preparation, administration and use by the patient;
(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered,
including their avoidance, and the action required if they occur;
(f) techniques for self-monitoring drug therapy;
(g) proper storage;
(h) prescription refill information;
(i) action to be taken in the event of a missed dose;
(j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or
drug; and
(k) the date after which the prescription should not be taken or used, or the beyond use date.

☐ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

☑ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information

33 ☐ ☐ Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication [UAC R156-17b-610(1)]

34 ☐ ☐ A pharmacy facility shall orally offer to counsel but shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses counseling. [UAC R156-17b-610(2)]

35 ☑ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

36 ☑ ☐ A pharmacy may only deliver a prescription drug to a patient or a patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or return to the pharmacy. [UCA 58-17b-602 (9)(a)(b)(i-ii)]

37 ☐ ☐ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee: [UAC R156-17b-608 (1-5)]

☑ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☑ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☐ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☑ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counselling.

☐ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment.

38 ☑ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]

- ☑ name, address, & phone number of pharmacy
- ☑ filling date or last dispensing date
- ☑ name of the prescriber
- ☑ trade, generic or chemical name *(Unless Otherwise Indicated by Prescriber)*
- ☑ serial number of prescription
- ☑ name of the patient or animal owner/species
- ☑ directions for use & cautionary statements
- ☑ amount dispensed & strength of dosage form
- ☑ beyond use date

39 ☑ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [UAC 58-1-502(6)& 16 CFR 1700.14]

40 ☑ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

41 ☑ ☐ The registered pharmacy does only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [UAC R156-17b-613(1) & CFR, Title 21, Chapter 11, Section 1311]

42 ☑ ☐ Prescription files, including refill information, are maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

43 ☑ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders. [UAC R156-37-602 (4) (a-b)]

44 ☑ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3) (5)]

45 ☑ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3) (6)]

46 ☐ ☑ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

47 ☐ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605 (3) (a-c)] ☐ N/A

48 ☑ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(e)(f)(i)(j)]

- ☑ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;
- ☑ the inventory records shall be maintained for a period of five years and be readily available for inspection
- ☑ the inventory shall be filed separately from all records
- ☐ the inventory may be taken either as the opening of the business or the close of business on the inventory date;
- ☑ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.
- ☑ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;
- ☑ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

49 ☐ ☐ n/a All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(7)]

50 ☐ ☐ n/a The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

51 ☑ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

52 ☐ ☐ n/a Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]

53 ☐ ☐ n/a The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]

54 ☐ ☐ n/a The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a (9)]

55 ☑ ☐ The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour dail or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]

56 ☑ ☐ In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, and identification number used by individual picking up dispensed drug. [UCA R156-37f-203 (4) (aa-cc)]

57 ☐ ☑ The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.

58 ☐ ☑ The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.

59 ☐ ☑ The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]

60 ☐ ☑ Does the pharmacy purchase any compound products from other entities for dispensing to patients? [UAC 58-17b-102(18)(b)(i)]

61 ☐ ☑ The facility is engaged in compounding with hazardous drugs as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.

62 ☐ ☑ The facility is engaged in simple, medium, or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (3)]

63 ☑ ☐ The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (3)]

COMMENTS

(2) Pharmacy has a current list of licenses.

(12) Staff has nametags.

(16) Pharmacy is clean and organized.

(20) 8 outdates were found in pharmacy stock.

(32) When mailing prescriptions outside telephone area code, required statement must be included.

(37) • SOPs for shipping must address that if prescription doesn't arrive in a timely manner of if it was compromised during shipment that the pharmacy will make provisions for replacement.

◦ Pharmacy is to provide info on what to do if package or drug is compromised during shipment.

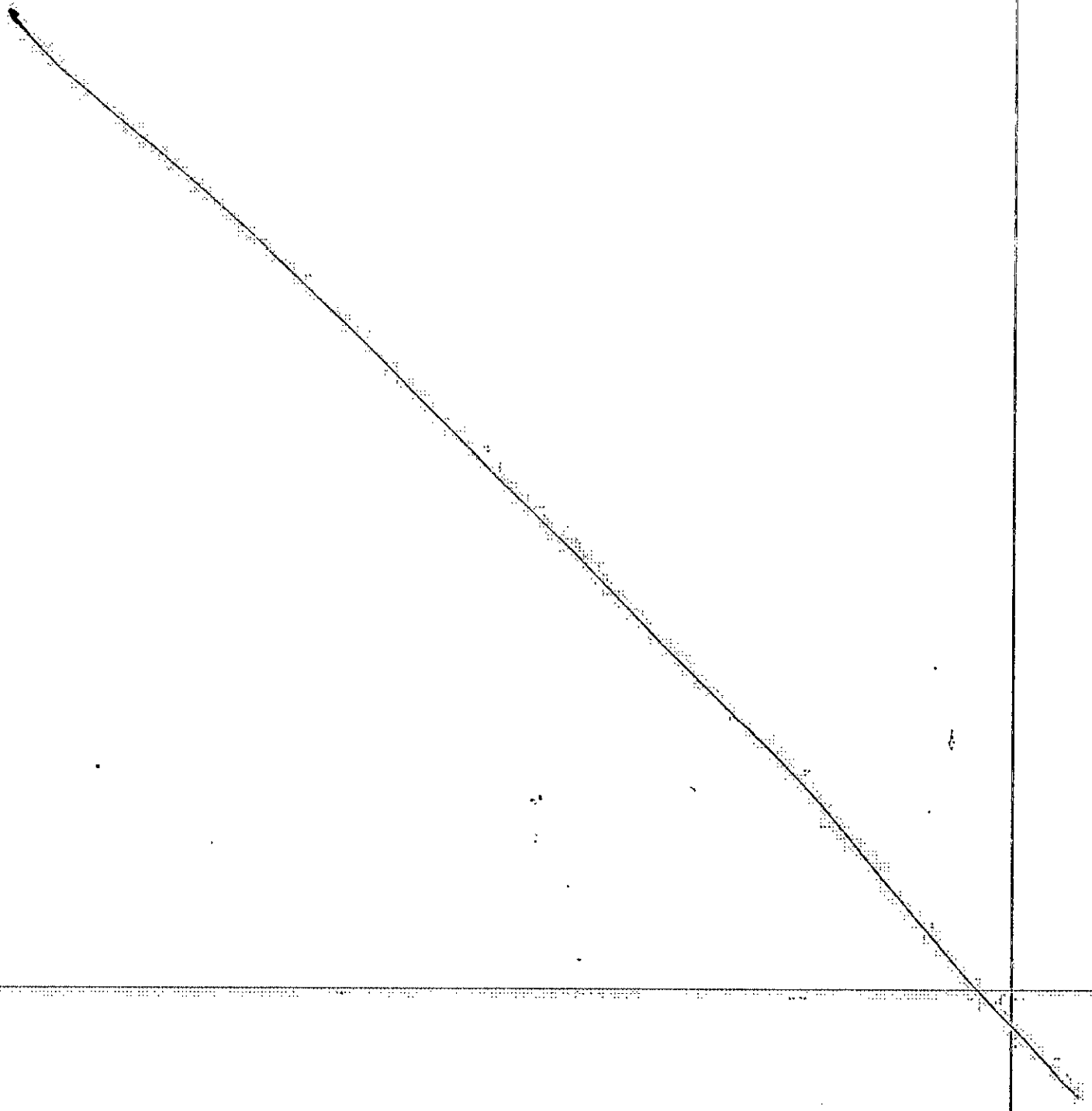
- Pharmacy does not carry controlled substances.

(46, 48) Pharmacy does not have yrly annual controlled substance inventories for the years 2019, 2020, 2021, or 2022.

◦ No automation.

◦ No nonsterile compounding.

(63) a sterile compounding inspection was conducted.



☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: Aleesha R Galeria Date: 07.06.2022

Name of Responsible Party (Print): Aleesha Galeria

Signature of Division Investigator: Travis Dobing Date: 7-6-2022

Name of Division Investigator (Print): Travis Dobing

Revised 4/2020

State of Utah
Department of Commerce

Division of Occupational and Professional Licensing
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STERILE COMPOUNDING

INSPECTION

☐ New Opening ☑ Regular

INFORMATION

Pharmacy Name: Oakstead Infusion Pharmacy, LLC. DBA: Oakstead Infusion Vital Care Date: 7/6/2022

Pharmacy License Number: 9704028-1704 Expiration Date: 09/30/2023

Controlled Substance License Number: 9704028-8913 Expiration Date: 09/30/2023

DEA Registration Number: FO5904556 Expiration Date: 12/31/2024

Pharmacy FEIN #: 47-5399800

Pharmacist-In-Charge (PIC): Aleesha Richman Galeria

Pharmacist-In-Charge License Number: 6537899-1701 Expiration Date: 09/30/2023

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met: (a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations. [UAC R156-17b-614a (3)]

	Yes	No	GENERAL OPERATIONS AND INFORMATION
			Which categories of compounding does the facility perform?
1.	☑	☐	The pharmacy does perform compounding identified as **low-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Low-Risk Level CSPs]*
			☑ The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.
			☑ The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/ device to prepare the CSP.
			☑ Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.
			☑ For a low-risk level preparation, in the absence of passing a sterility teste (see Sterility Tests <71>) the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see General Notices and Requirements), and for 45 days in solid frozen state between -25°and -10°.
	☑	☐	The pharmacy does perform compounding identified as **medium-risk.** When CSPs are compounded aseptically under Low-Risk Conditions and one or more of the following conditions exist, such CSPs are at a medium risk of contamination. [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- Medium-Risk Levels CSPs]*
			☑ Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered to either multiple patients or to one patient on multiple occasions.
			☑ The compounding process includes complex aseptic manipulations other than the single-volume transfer.
			☑ The compounding process requires unusually long duration, such as that required to compete dissolution or homogenous mixing.
			☑ For a medium-risk preparation, in the absence of passing a sterility test (see Sterility Tests <71>0, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see Generals Notices and Requirements), and for 45 days in solid frozen state between 25°and -10°.

☐ ☑ The pharmacy does perform compounding identified as **high-risk** [USP-NF Chapter 797- *USP Microbial Contamination Risk Levels- High-Risk Levels CSPs]*

☐ Non sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g. oral), are incorporated or a non-sterile device is employed before terminal sterilization.

☐ Any of the following are exposed to air quality worse than ISO 5 for more than 1 hour (see *Immediate-Use CSPs*):

- ☐ Sterile contents of commercially manufactured products,
- ☐ CSPs that lack effective antimicrobial preservative, and
- ☐ Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs

☐ Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment)*.

☐ Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.

☐ It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendia specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection under Pharmaceutical Compounding- Non-Sterile Preparations <795>)*.

☐ In the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements)*, for not more than 3 days at a cold temperature (see *General Notices and Requirements)*, and for 45 days in a solid frozen state between 25° and -10°.

☐ ☑ n/a **Immediate-use provision in intended only for those situation where there is a need for emergency or immediate patient administration of a CSP.** Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs. [USP-NF Chapter 797- *Immediate-use CSPs*]

☐ ☑ **Immediate-use CSPs** are exempt from the requirements described for Low-Risk Label CSPs only when all of the following are met: [USP-NF Chapter 797- *Immediate-use CSPs]*

☐ The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturer's original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.

☐ Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.

☐ During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mixups with other CSPs, and direct contact of outside surfaces.

☐ Administration begins not later than 1 hour following the start of the preparation of the CSP.

☐ Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.

☐ If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

2. ☑ ☐ Does the facility dispense sterile compounded preparations pursuant to a prescription?

3. ☐ ☑ Does the facility make sterile compounded preparations that are delivered to a practitioner for administration to a patient in an office, clinic, or facility?

4. ☐ ☑ A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for

office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]

5. ☑ ☐ Does the facility distribute sterile compounded preparations to hospitals, clinics, or surgery centers?

6. ☐ ☑ Does the facility have a sales force that distributes samples containing active ingredients? List samples.

7. ☐ ☑ Does the facility compound sterile preparations for veterinary use?

8. ☐ ☑ Is the facility registered with the FDA as an "Outsourcing Facility"?

9. ☑ ☐ The facility does compound:

☐ allergen extracts	☐ baths and soaks for live organs and tissues
☑ parental solutions	☐ oral or nasal inhalation preparations
☐ parenteral suspensions	☐ irrigations for wounds and body cavities
☑ preservative free parenterals	☐ ophthalmic preparations

10. ☐ ☑ Does the facility compound investigational drugs? List.

11. ☑ ☐ The facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UAC 58-17b-102(18)(b)(ii)]

12. ☑ ☐ The facility does not prepare a prescription drug for sale to another pharmacist or pharmaceutical facility. [UAC 58-17b-102(18)(b)(i)]

13. ☑ ☐ The facility does not prepare a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons. [UAC 58-17b-102(18)(b)(iii)]

14. ☐ ☑ Does the pharmacy makes sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients?

15. ☐ ☑ Bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness. [UAC R156-17b-614a(3)(c)(i)(ii)]

16. ☐ ☑ Does the facility have a lyophilizer?

17. ☑ ☐ **The compounding facility shall have written, properly approved SOPs** designed to ensure the quality of the environment in which a CSP is prepared. [USP-NF Chapter 797-*Responsibility of Compounding Personnel-Suggested Standard Operating Procedures (SOPs)]*

a. ☑ Procedures for **measuring, mixing, dilution, purification, sterilization, packaging, and labeling** conform to the correct sequence and quality established for the specified CSP. [USP-NF Chapter 797- *Responsibility of Compounding Personnel*]

b. ☑ **All cleaning and disinfecting** practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control and Disinfecting the Compounding Area*]

- ☑ ISO Class 5 PEC (e.g. LAFW, BSC, CAI, CACI)
- ☑ Counters and easily cleanable work surfaces
- ☑ Floors
- ☑ Walls
- ☑ Ceiling
- ☑ Storage Shelving

c. ☑ It is necessary that **equipment, apparatus, and devices** used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. [USP-NF Chapter 797- *Element of Quality Control, Equipment]*

- ☑ Equipment calibration
- ☑ Annual maintenance
- ☑ Monitoring for proper function and controlled procedures for use of the equipment and specified time frames for these activities
- ☑ Routine maintenance and frequencies

d. ☑ The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for **maintaining and working within the PEC** area shall be written and followed. The policies and procedure will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Control]*

e. n/a ☐ When compounding activities require **the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling** procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross contamination. [USP-NF Chapter 797- *Environmental Quality and Control- Additional Personnel Requirements*]

f. ☑ **Double-checking compounding** accuracy shall be followed for every CSP during preparation and immediately prior to release. [USP-NF Chapter 797- *Preparation Release Checks and Tests, Compounding Accuracy Checks*]

g. n/a ☐ When **high-risk level CSPs are dispensed before receiving the results of their sterility tests**, there shall be a written procedure requiring daily observations of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Sterility Testing*]

h. ☐ **Verifying the correct identity and quality** of CSPs before they are dispensed and administered: [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests, Identity and Strength Verification of Ingredients*]

- ☐ Labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
- ☐ That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
- ☐ That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

i. ☑ To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the **determination of the BUDs** for all compounded products. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions. [USP-NF Chapter 797- *Storage and Beyond-Use Dating*]

j. ☑ The **compounding procedures and sterilization methods** for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Stability*]

k. ☑ Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for **unit-by-unit physical inspection preparatory to use** is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use. [USP-NF Chapter 797- *Elements of Quality Control- Ingredients and Devices- Sterile Ingredients and Devices*]

l. ☑ Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper **packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions.** The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks involving any of these responsibilities, the policies and procedures

encompassing those tasks should be developed by compounding supervisors. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs*]

m. ☑ Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as **transport, handling, and placement into storage, may be fulfilled by noncompounding personnel** who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures. [USP- NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packaging, Handling, and Transport*]

n. ☑ **When CSPs are distributed to locations outside the premises** in which they are compounded, compounding personnel select packing containers and materials that are **expected to maintain physical integrity, sterility, and stability of CSPs during transit**. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Packing CSPs for Transit*]

o. ☑ SOPs must exist to ensure that **storage conditions in the patient-care setting** are suitable for the CSP-specific storage requirements. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs, Use and Storage*]

☑ Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8°

☐ and the monthly inspection of all drug storage locations by compounding personnel.

p. ☑ The SOP manuals of compounding facilities shall describe **specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation** claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP. [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

Personnel Training and Requirements

18. ☑ ☐ A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. **Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs** (see Personnel Training and Evaluation in Aseptic Manipulation Skills and Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures). [USP-NF Chapter 797 - *Elements of Quality Control*]

19. ☑ ☐ **Personnel who prepare CSPs shall be trained** conscientiously and skillfully by **expert personnel, multi-media instructional sources, and professional publications** in the theoretical principles and practical skills of **garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures**. [USP-NF Chapter 797- *Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

20. ☑ ☐ Compounding personnel shall complete: [USP-NF Chapter 797- *Appendices- Appendix I-Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*]

☑ didactic training, ☐ pass written competence assessments,

☑ undergo skill assessment using observational audit tools, ☑ and media-fill testing.

21. ☑ ☐ **Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures** (see *Personnel Cleansing* and *Garbing* under *Personnel Training and Evaluation in Aseptic Manipulation Skills* above). **The visual observation shall be documented** on a form such as the Sample Form for

Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel [see Appendix III] and maintained to provide a permanent record and long-term assessment of personnel competency. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

22. ☑ ☐ **Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding** because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling **shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs.** All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

23. ☑ ☐ **Sterile contact agar plates shall be used to sample the gloved fingertips** of compounding personnel **after garbing** in order to assess garbing competency and **after completing the media-fill preparation** (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

24. ☑ ☐ **All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use.** Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see Incubation Period). **After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs** using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

25. ☑ ☐ **After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures.** Records of these evaluations will be maintained using a form such as the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel (see Appendix IV) and maintained to provide a permanent record of and long-term assessment of personnel competency. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Competency Evaluation of Garbing and Aseptic Work Practice*]

26. ☑ ☐ **Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding.** Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies. [USP-NF Chapter 797- *Personnel Training and Evaluation in Aseptic Manipulation Skills*]

27. ☐ ☐ **Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during initial personnel training on cleaning procedures, during changes in cleaning staff,** and at the **completion of any media-fill test procedure** (see

Cleaning and Disinfecting of Compounding Areas). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures, Surface Cleaning and Disinfection Sampling and Assessment*]

28. ☑ ☐ **In the event that cleaning and disinfecting procedures are also performed by other support personnel** (e.g., institutional environmental services, housekeeping), thorough training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support **personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures*]

29. ☐ ☐ n/a **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The **training shall include** at least the following: [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]
- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

Handwashing and Garbing

30. ☑ ☐ **When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates.** Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. **Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see Table 1) and ISO Class 7 (see Table 1) compounding areas until their conditions are remedied.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

31. ☑ ☐ **Before entering the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), **compounding personnel shall remove personal outer garments** (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); **all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings** (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). **The wearing of artificial nails or extenders is prohibited** while working in the sterile compounding environment. **Natural nails shall be kept neat and trimmed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

32. ☑ ☐ **Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.** Garbing activities considered the dirtiest include donning of ☑ dedicated shoes or shoe covers, ☐ head and facial hair covers (e.g., beard covers in addition to face masks), and ☑ face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

33. ☑ ☐ **After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area.** The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lintfree disposable towels or an electronic hand dryer. ☑ **After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned.** Gowns designated for buffer-area-use shall be worn, and **preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

34. ☑ ☐ **Once inside the buffer area or segregated compounding area** (see Low-Risk Level CSPs with 12-Hour or Less BUD), **and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed**

using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

35. ☑ ☐ **Sterile gloves shall be the last item donned before compounding begins.** Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. **Routine application of sterile 70% IPA shall occur throughout the compounding process** and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched. **Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.** Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel. [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

36. ☑ ☐ **When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

37. ☐ ☐ n/a **During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see Table 1) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see Table 1) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon reentering the ISO Class 7 (see Table 1) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see Table 1) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.** [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Cleansing and Garbing*]

38. ☑ ☐ **Cleaning and disinfecting shall occur before compounding is performed.** Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water soluble solid residues are removed with sterile water (for injection or irrigation) and lowshedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

Cleaning Requirements

39. ☑ ☐ Cleaning and disinfecting surfaces in the **LAFWs, BSCs, CAIs, and CACIs** are the most critical practices before the preparation of CSPs. Consequently, **such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

40. ☑ ☐ **Work surfaces in the ISO Class 7 (see Table 1) buffer areas and ISO Class 8 (see Table 1) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris** shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see Table 1) air quality (see Disinfectants and Antiseptics <1072>). [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

41. ☑ ☐ **Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress.** Mopping shall be performed by trained personnel using approved agents and procedures described in the

written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

42. ☑ ☐ In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

43. ☑ ☐ **Cleaning and disinfecting agents** are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see Appendix II). **Their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

44. ☑ ☐ **All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding**, preferably composed of synthetic micro fibers, and **dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.** Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned. [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

45. ☑ ☐ **Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent** (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant **shall be allowed to dry, during which time the item shall not be used for compounding purposes.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

46. ☑ ☐ Facilities and Environmental Monitoring

Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. **Surface sampling shall be performed in all ISO classified areas on a periodic basis.** Sampling can be accomplished using contact plates or swabs, and it **shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form.** The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>). [USP-NF Chapter 797- *Environmental Quality and Control - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures- Surface Cleaning and Disinfection Sampling and Assessment*]

47. ☑ ☐ The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. **Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797- *Environmental Quality and Control - Action Levels, Documentation, and Data Evaluation*]

48. ☑ ☐ Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. [USP-NF Chapter 797-Environmental Quality and Control- Additional Personnel Requirements]

49. ☑ ☐ **Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide for the orderly placement of equipment and materials to prevent mixups** among ingredients, containers, labels, in-process materials, and finished preparations and is designed,

arranged, and used to prevent adventitious cross-contamination. **Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area** (see Pharmaceutical Compounding—Sterile Preparations <797>, Environmental Quality and Control). [USP-NF Chapter 795- *Compounding Facilities*]

50. ☑ ☐ The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

51. ☑ ☐ Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

52. ☑ ☐ Any other penetrations through the ceiling or walls shall be sealed. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

53. ☑ ☐ The buffer area shall not contain sources of water (sinks) or floor drains. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

54. ☑ ☐ Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

55. ☑ ☐ Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

56. ☑ ☐ There shall be some demarcation designation that separates the ante-area from the buffer area. [USP-NF Chapter 797-Environmental Quality and Control- Additional Personnel Requirements]

57. ☑ ☐ **To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility.** Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, −25° and −10° (see General Notices and Requirements) if needed to achieve freezing, and the media-specific temperature range for microbial culture media. **A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations.** Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. **If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.** [USP-NF Chapter 797- *Storage and Beyond Use Dating- Monitoring Controlled Storage Areas*]

58. ☑ ☐ **Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see Table 1), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered.** Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following: [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES)- Testing- Total Particle Counts*]

☑ ISO Class 5: not more than 3520 particles 0.5 mm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;

☐ ISO Class 7: not more than 352,000 particles of 0.5 mm size and larger per cubic meter of air for any buffer

area;
☑ ISO Class 8: not more than 3,520,000 particles or 0.5 mm size and larger per cubic meter of air for any ante-area.

59. ☑ ☐ **All certification records shall be maintained and reviewed by supervising personnel or other designated employees** to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Total Particle Counts*]

60. ☑ ☐ **A pressure gauge or velocity meter shall be installed to monitor the pressure** differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

61. ☑ ☐ **The results shall be reviewed and documented on a log at least every work shift** (minimum frequency shall be at least daily) or by a continuous recording device. [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

62. ☑ ☐ **The pressure between the ISO Class 7 (see Table 1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.** [USP-NF Chapter 797- *Environmental Quality and Control- Viable and Nonviable Environmental Sampling (ES) Testing- Pressure Differential Monitoring*]

63. ☑ ☐ **The buffer area shall maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm and larger particles under dynamic operating conditions.** The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

64. ☑ ☐ For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05- inch water column is required. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

65. ☑ ☐ For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. [USP-NF Chapter 797 - *Environmental Quality and Control- Facility Design and Environmental Controls*]

66. ☑ ☐ **An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30.** The PEC is a good augmentation to generating air changes in the air supply of an area, but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

67. ☑ ☐ **HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall,** creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

68. ☑ ☐ **Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.** Only the **furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.** Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other

activities associated with the proper maintenance of the item. [USP-NF Chapter 797- *Environmental Quality and Control- Facility Design and Environmental Controls*]

69. ☑ ☐ Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. **Buffer areas are designed to maintain at least ISO Class 7 (see Table 1) conditions for 0.5-mm particles under dynamic conditions and ISO Class 8 (see Table 1) conditions for 0.5-mm and larger particles under dynamic conditions for the ante-areas.** [USP-NF Chapter 797 *Environmental Quality and Control, Facility Design and Environmental Controls*]

70. ☑ ☐ **PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas)** are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. **Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Nonviable Particle Testing Program*]

71. ☑ ☐ PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see Table 1) environment for the exposure of critical sites. **PECs shall maintain ISO Class 5 (see Table 1) or better conditions for 0.5-mm particles (dynamic operating conditions) while compounding CSPs.** [USP-NF Chapter 797 -*Environmental Quality and Control, Facility Design and Environmental Controls*]

72. ☑ ☐ **The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.** For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

73. ☑ ☐ PECs (LAFWs, BSCs, CAIs, and CACIs) **shall be located within a restricted access ISO Class 7 (see Table 1) buffer area (see Figure 1),** with the following CAI/CACI exceptions below: [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
☑ Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
☐ Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see Table 1) environment.
☑ PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

74. ☐ ☐ n/a **CAIs and CACIs shall be placed in an ISO Class 7 (see Table 1) buffer area unless they meet all of the following conditions:** [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]
☐ The isolator shall provide isolation from the room and maintain ISO Class 5 (see Table 1) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
☐ Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see Table 1) levels during compounding operations.
☐ Not more than 3520 particles (0.5 mm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.

75. ☐ ☐ n/a **If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see Table 1) buffer area,** then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

76. ☐ ☐ n/a When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see Table 1) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is

allowed after material transfer before and during compounding operations. [USP-NF Chapter 797 - *Environmental Quality and Control, Facility Design and Environmental Controls*]

77. ☑ ☐ Airborne contamination control is achieved in the PEC through the use of HEPA filters. **The airflow in the PEC shall be unidirectional (laminar flow),** and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate **contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see Table 1) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations.** Proper design and control prevents turbulence and stagnant air in the critical area. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

78. ☑ ☐ **In situ air pattern analysis via smoke studies shall be conducted** at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [USP-NF Chapter 797- *Environmental Quality and Control, Facility Design and Environmental Controls*]

79. ☑ ☐ **Environmental sampling shall occur as part a comprehensive quality management program** and shall occur minimally under any of the following conditions: [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing*]
- ☑ as part of the commissioning and certification of new facilities and equipment;
- ☑ following any servicing of facilities and equipment;
- ☑ as part of the re-certification of facilities and equipment [i.e., every 6 months];
- ☐ in response to identified problems with end products or staff technique; or
- ☑ in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

80. ☑ ☐ Sampling Plan—**An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 (see Table 1) environment and in the ISO Class 7 and 8 (see Table 1) areas and in the segregated compounding areas at greatest risk of contamination** (e.g., work areas near the ISO Class 5 [see Table 1] environment, counters near doors, pass-through boxes). **The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

81. ☑ ☐ Growth Medium—**A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.** Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program, Sampling Plan*]

82. ☑ ☐ Viable Air Sampling—**Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments** (LAFWs, CAIs, clean room or buffer areas, and ante-areas) **shall be performed by properly trained individuals for all compounding risk levels. Impaction shall be the preferred method of volumetric air sampling.** Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

83. ☑ ☐ **For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning.** Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see Table 1] PEC and environments). [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

84. ☑ ☐ **For low-risk level CSPs with 12-hour or less BUD prepared in a PEC** (LAFWs, BSCs, CAIs) **that maintains an**

ISO Class 5 (see Table 1), air sampling shall be performed at locations inside the ISO Class 5 (see Table 1) environment and other areas that are in close proximity to the ISO Class 5 (see Table 1) environment during the certification of the PEC. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

85. ☑ ☐ Air Sampling Devices—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. **A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

86. ☑ ☐ Air Sampling Frequency and Process—**Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment.** If compounding occurs in multiple locations within an institution (e.g., main pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events. [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

87. ☑ ☐ Action Levels, Documentation, and Data Evaluation—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. **Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

88. ☑ ☐ **Any cfu count that exceeds its respective action level (see Table 2) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted.** Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. **The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.** [USP-NF Chapter 797 - *Environmental Quality and Control, Viable and Nonviable Environmental Sampling (ES) Testing, Environmental Viable Airborne Particle Testing Program*]

89. ☑ ☐ The intermediate precision of the ACD can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, **compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time.** [USP-NF Chapter 797 - *Elements of Quality Control- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding- Precision*]

90. ☑ ☐ **Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients.** In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions. [USP-NF Chapter 797 - *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs*]

91. ☑ ☐ CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Use and Storage*]

Documentation

All facilities that dispense prescriptions must comply with the record keeping requirements of their State Boards of Pharmacy. When a facility compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation as described in this section. [UAC R 156-17b-614a (3)(d)]

92. ☑ ☐ A master formulation record shall be approved by a pharmacist or DMP for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master formulation record shall be used as the compounding record from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet may be stored electronically and shall contain at a minimum: [UAC R156-17b-614a(3)(e)(i-xiii)]

☑ official or assigned name
☑ strength
☑ dosage form of the preparation
☑ calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients dosage form of the preparation
☑ description of ingredients and their quantities
☑ compatibility and stability information, including references when available
☑ equipment needed to prepare the preparation
☑ container used in dispensing
☑ packaging and storage requirements
☑ description of final preparation
☑ quality control procedures and expected results;
☑ mixing instructions, which shall include: ☑ order of mixing ☑ mixing temperatures or other environmental controls ☑ duration of mixing ☑ other factors pertinent to the replication of the preparation as compounded
☑ sample labeling information, which shall contain, in addition to legally required information: ☑ generic name and quantity or concentration of each active ingredient ☑ assigned beyond use date ☑ storage conditions ☑ prescription or control number, whichever is applicable

93. ☑ ☐ A compounding record for each batch of sterile or non-sterile pharmaceuticals shall document the following: [UAC R156-17b-614a(3)(f) (i-xix)]

☑ official or assigned name;
☑ strength and dosage of the preparation;
☑ Master Formulation Record reference for the preparation;
☑ names and quantities of all components
☑ sources, lot numbers, and expiration dates of components;
☑ total quantity compounded;
☑ name of the person who prepared the preparation
☑ name of the compounder who approved the preparation
☑ name of the person who performed the quality control procedures
☑ date of preparation
☑ assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable
☑ duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain: ☑ active ingredients ☑ beyond use date ☑ storage conditions and ☐ lot number;
☑ proof of the duplicate labeling information, which proof shall: ☑ be kept at the pharmacy ☑ be immediately retrievable ☑ include an audit trail for any altered form; and ☑ be reproduced in: the original format that was dispensed, an electronic format, or a scanned electronic version
☑ description of final preparation
☑ results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids); and
☑ documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

94. ☑ ☐ Compounding records including the master worksheet, preparation worksheet, and MSDS files shall be kept for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

95. ☑ ☐ The facility maintains documentation regarding an ongoing quality control program that monitors and evaluates personnel performance, equipment and facility's compliance with following the USP-NF Chapters 795 and 797 standards. [UAC R156-17b-614a(3)(h)]

96. ☑ ☐ Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. [USP-NF Chapter 797- *Elements of Quality Control- Equipment*]

Compounding Procedures

97. ☑ ☐ **Opened or needle-punctured single-dose containers,** such as bags, bottles, syringes, and vials of sterile products and CSPs **shall be used within 1 hour if opened in worse than ISO Class 5** (see Table 1) air quality (see Immediate-Use CSPs), **and any remaining contents must be discarded.** [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

98. ☑ ☐ ☑**Single-dose vials exposed to ISO Class 5** (see Table 1) **or cleaner air may be used up to 6 hours after initial needle puncture.** ☑**Opened single-dose ampuls shall not be stored for any time period.** ☑**Multiple-dose containers** (e.g., vials) **are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives.** The ☑**BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days** (see Antimicrobial Effectiveness Testing <51>) unless otherwise specified by the manufacturer. [USP-NF Chapter 797- *Single-Dose and Multiple-Dose Containers]*

99. ☑ ☐ Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. **The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.** [USP-NF Chapter 797- *Environmental Quality and Control - Cleaning and Disinfecting the Compounding Area*]

100. ☑ ☐ Pharmacy Bulk Package (see Containers for Injections under Injections <1>)—A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. **The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents.** The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). **Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.** [USP-NF Chapter 797- *Definitions*]

101. ☑ ☐ **The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method** (see Methods of Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility, Sterilization Methods*]

102. ☑ ☐ Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. [USP-NF Chapter 797 - Exposure of Critical Sites]

103. ☐ ☐ n/a **All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test** (see Sterility Tests <71>) **before they are dispensed or administered.** [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Sterility Testing*]

104. ☐ ☐ n/a **All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins** (see Bacterial Endotoxins Test <85> and Pyrogen Test <151>). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in Bacterial Endotoxins Test <85> referenced above for the appropriate route of administration. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Bacterial Endotoxin (Pyrogen) Testing*]

105. ☐ ☑ **Does the facility participate in the following:**
☐ Hazardous Drugs ☐ Radiopharmaceuticals ☐ Allergen Extracts as CSPs

Hazardous Drugs

106. ☐ ☐ n/a **All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace.** [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]

107. ☐ ☐ **Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.** The training **shall include** at least the following: [USP- NF Chapter 797- *Hazardous Drugs as CSPs*]
- ☐ safe aseptic manipulation practices;
- ☐ negative pressure techniques when utilizing a BSC or CACI;
- ☐ correct use of CSTD devices;
- ☐ containment, cleanup, and disposal procedures for breakages and spills; and
- ☐ treatment of personnel contact and inhalation exposure.

108. ☐ ☐ Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

109. ☐ ☐ Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

110. ☐ ☐ Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

111. ☐ ☐ Hazardous drugs shall be prepared in an ISO Class 5 (see Table 1) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

112. ☐ ☐ Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

113. ☐ ☐ n/a **All hazardous drugs shall be prepared in a BSC5 or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see Table 1) BSC or CACI shall be placed in an ISO Class 7 (see Table 1) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see Table 1) or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization.** [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

114. ☐ ☐ If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

115. ☐ ☐ **When closed-system vial-transfer devices** (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) **are used, they shall be used within the ISO Class 5 (see Table 1) environment of a BSC or CACI.** The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

116. ☐ ☐ **Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices.** PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

117. ☐ ☐ Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

118. ☐ ☐ All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

119. ☐ ☐ **Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel** who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs **shall be trained** in appropriate procedures to protect themselves and prevent contamination. [USP-NF Chapter 797- *Hazardous Drugs as CSPs*]

Radiopharmaceuticals

120. ☐ ☐ For the purposes of this chapter, **radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container (see Injections <1>) shall be designated as, and conform to, the standards for Low-Risk Level CSPs.** These radiopharmaceuticals **shall be compounded using appropriately**

121. ☐ ☐ **shielded vials and syringes in a properly functioning and certified ISO Class 5 (see Table 1) PEC located in an ISO Class 8 (see Table 1) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.** [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

Radiopharmaceuticals prepared as Low-Risk Level CSPs with 12-Hour or Less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not cross a line of

122. ☐ ☐ demarcation into the segregated compounding area. [USP-NF Chapter 797- *Radiopharmaceuticals as CSPs*]

Allergen Extracts as CSPs

Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision. **Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter only when all of the following criteria are met:** [USP-NF Chapter

123. ☐ ☐

n/a

797- Allergen Extracts as CSPs]

☐ The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).

☐ All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

☐ Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.

☐ Compounding personnel don hair covers, facial hair covers, gowns, and face masks.

☐ Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.

☐ Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

☐ Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.

☐ Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.

☐ The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).

☐ The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.

☐ Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Sterilization

124. ☐ ☐ Does the facility participate in the following:

☐ Filter Sterilization in an ISO class 5 ☐ Steam Sterilization ☐ Dry Heat Sterilization

125. ☐ ☐ **(Filter Sterilization in an ISO class 5)**

Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. **Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 mm.** They shall be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see High-Risk Conditions in High-Risk Level CSPs). [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

126. ☐ ☐ **The compounding supervisor shall ensure,** directly or from appropriate documentation, that **the filters** are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

127. ☐ ☐ The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

128. ☐ ☐ Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

129. ☐ ☐ Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. [USP-NF Chapter 797 - *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Filtration*]

130. ☐ ☐ n/a

(Steam Sterilization)
The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see Steam Sterilization under Sterilization and Sterility Assurance of Compendial Articles <1211>). **To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs.** An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

131. ☐ ☐ Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. **Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 mm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.** [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

132. ☐ ☐ The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of Bacillus stearothermophilus (see Biological Indicators <1035>) and other confirmation methods such as temperature-sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility- Sterilization Methods- Sterilization of High-Risk Level CSPs by Steam*]

133. ☐ ☐ **(Dry Heat Sterilization)**
Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. **Heated filtered air shall be evenly distributed throughout the chamber by a blower device.** [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

134. ☐ ☐ **Dry heat shall be used only for those materials that cannot be sterilized by steam,** when either the moisture would damage the material or the material is impermeable. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

135. ☐ ☐ During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

136. ☐ ☐ The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

137. ☐ ☐ The effectiveness of dry heat sterilization shall be verified using appropriate BIs of Bacillus subtilis (see Biological Indicators <1035>) and other confirmation methods such as temperature-sensing devices (see Sterilization and Sterility Assurance of Compendial Articles <1211> and Sterility Tests <71>). [USP-NF Chapters 797- *Verification of Compounding Accuracy and Sterility- Sterilization Method- Sterilization of High-Risk Level CSPs by Dry Heat*]

Finished Preparation Release Checks and Tests

138. ☑ ☐ **All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.** The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

[USP- NF Chapter 797- *Finished Preparation Release Checks and Tests- Inspection of Solution Dosage Forms and Review of Compounding Procedures*

139. ☑ ☐ **The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.** When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately. [USP-NF Chapter 797- *Verification of Compounding Accuracy and Sterility*]

140. ☐ ☐ n/a The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum: [UAC R156-17b-614a (3)(g)(i-vi)
- ☐ the unique lot number assigned to the batch;
- ☐ all active solution and ingredient names, amounts strengths and concentrations, where applicable
- ☐ quantity
- ☐ beyond use date and time, when applicable
- ☐ appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and
- ☐ device-specific instructions, where appropriate.

141. ☑ ☐ All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in Section 58-17b-602 the following: [R156-17b-614a (3)(h)(i)(ii)(iii)
- ☑ generic name a quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
- ☑ assigned compounding record or lot number; and
- ☐ "this is a compounded preparation" or similar language

Packaging and Storage

142. ☑ ☐ Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

143. ☑ ☐ Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Packing and Transporting CSPs- Transit of CSPs*]

144. ☑ ☐ Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances: [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSP- Storage in Locations Outside Compounding Facilities*]
- ☑ Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
- ☑ Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

145. ☑ ☐ **Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs.** CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients. [USP-NF Chapter 797- *Finished Preparation Release Checks and Tests- Monitoring Controlled Storage Areas*]

146. ☑ ☐ Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. [USP-NF Chapter 797- *Storage and Beyond-use Dating*]

Quality Assurance Program

147. ☑ ☐ The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. **Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned.** This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse-events and incident reporting programs. [USP-NF Chapter 797- *Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs- Education and Training*]

148. ☑ ☐ **A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter.** Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed. Characteristics of a QA program include the following: [USP-NF Chapter 797- *Quality Assurance (QA) Program*]

- ☑ Formalization in writing;
- ☑ Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
- ☑ Description of specific monitoring and evaluation activities;
- ☑ Specification of how results are to be reported and evaluated;
- ☑ Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
- ☑ Delineation of the individuals responsible for each aspect of the QA program.

149. ☑ ☐ A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: [USP-NF Chapter 797- *Responsibilities of Compounding Personnel*]

- ☑ accuracy and precision of measuring and weighing;
- ☑ the requirement for sterility;
- ☑ methods of sterilization and purification;
- ☑ safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter;
- ☑ pH;
- ☑ labeling accuracy and completeness;
- ☑ BUD assignment;
- ☑ and packaging and storage requirements.

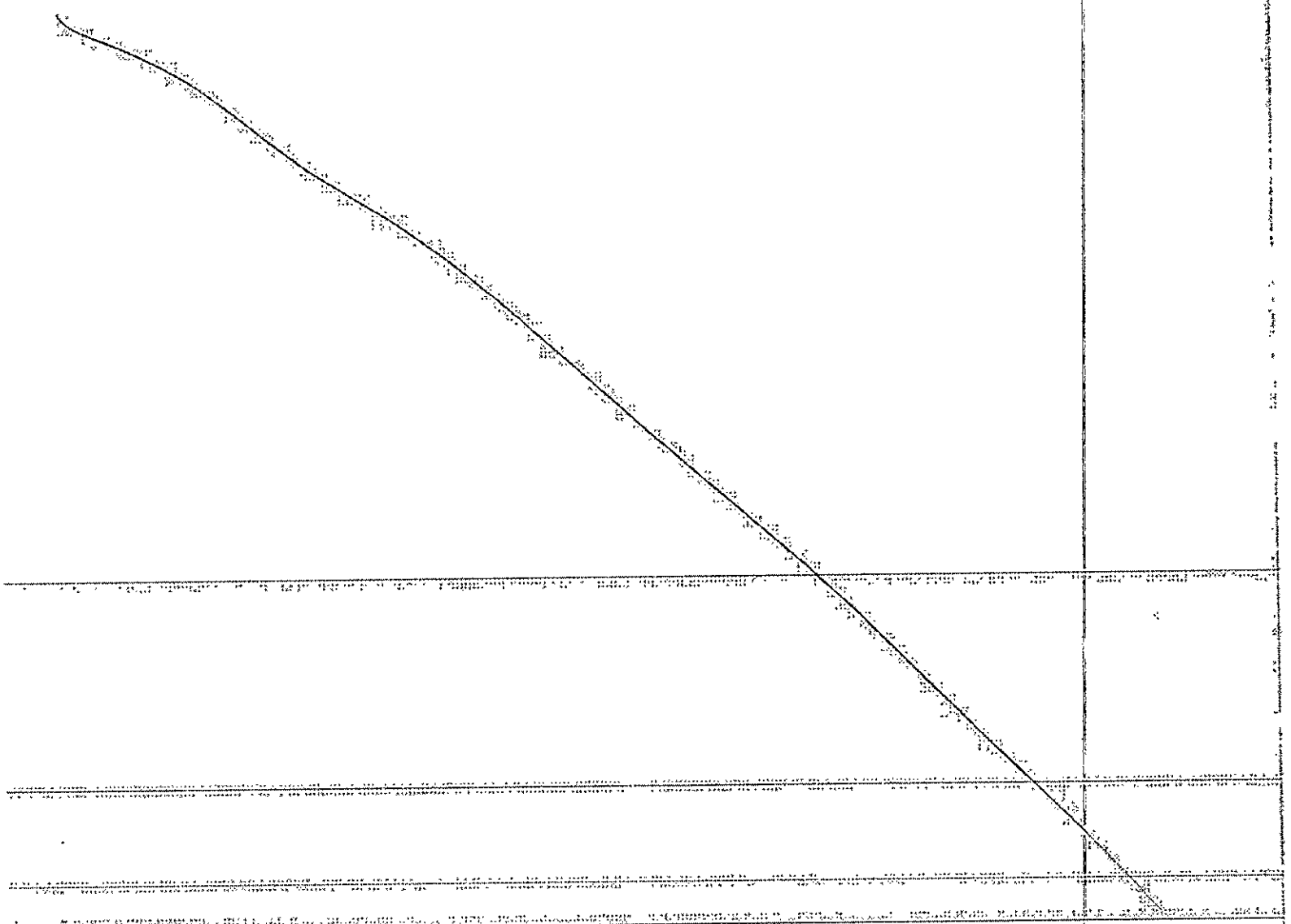
150. ☑ ☐ Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. **Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.** [USP-NF Chapter 797- *Patient Monitoring and Adverse Events Reporting*]

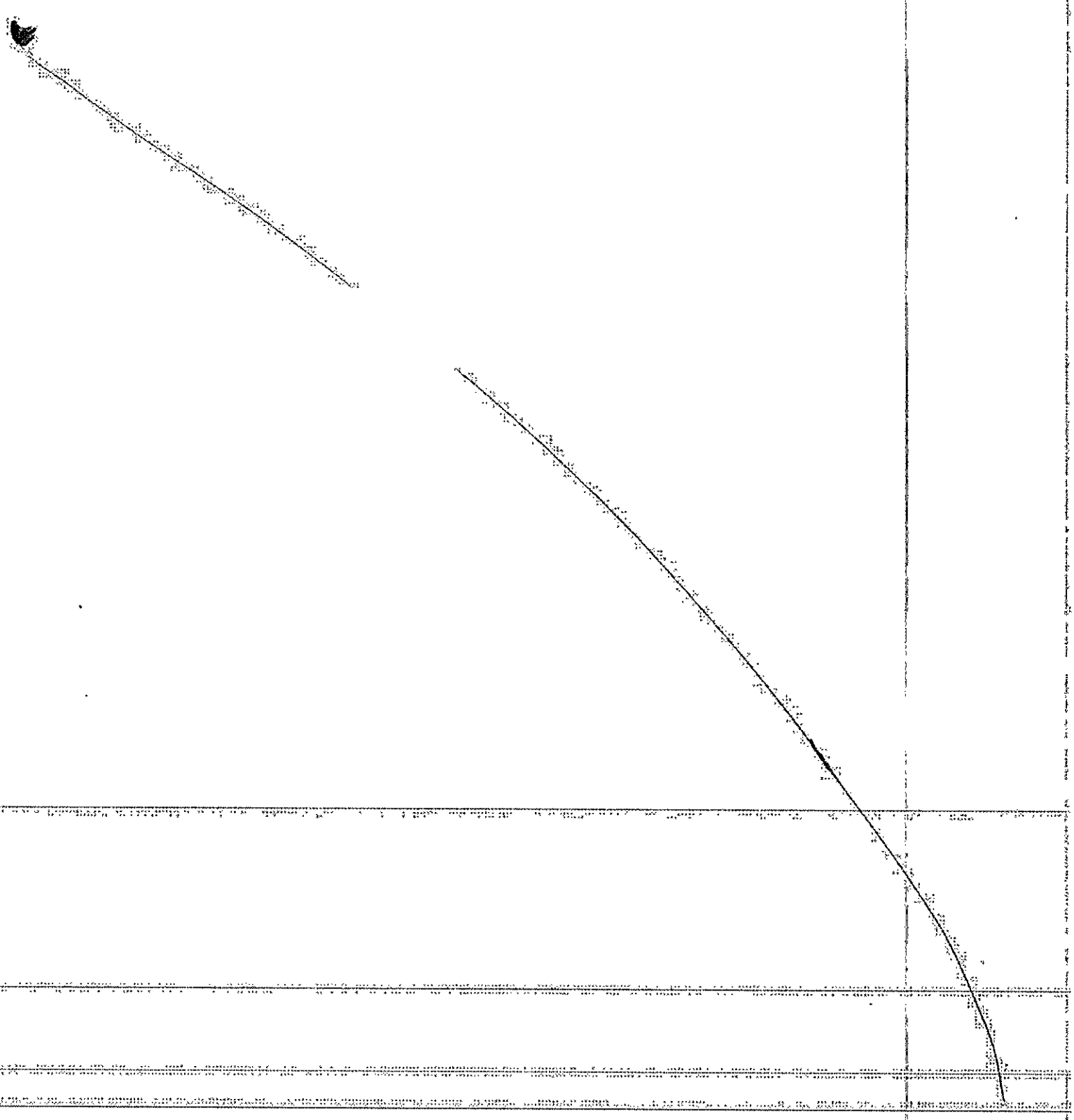
COMMENTS
(Use an additional sheet if necessary.)

(1) Pharmacy is engaged in ~~[illegible]~~ low and medium risk compounding.

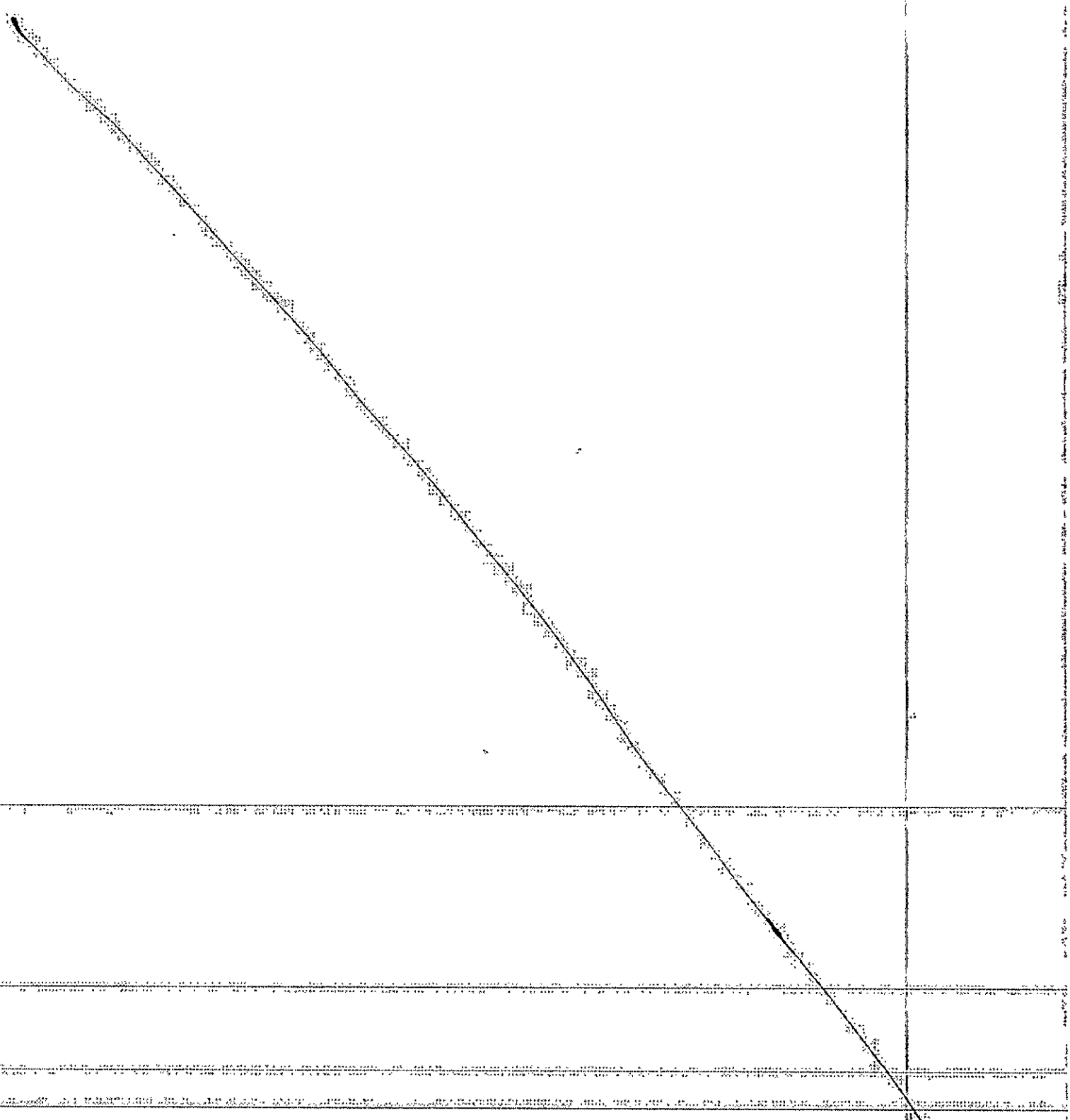
(7) SOPs are compliant.

- Training records are compliant.
- Pharmacy is not compounding with hazardous drugs.
- Certification records show no issues.
- Pharmacy is not sterilizing or conducting high-risk compounding.





• Heber M. Wells Building • 160 East 300 South • P.O. Box 146741 • Salt Lake City, UT 84114-6741 •
Telephone (801) 530-6628 • Toll-free in Utah (866) 275-3675 • Fax (801) 530-6301 • www.dopl.utah.gov



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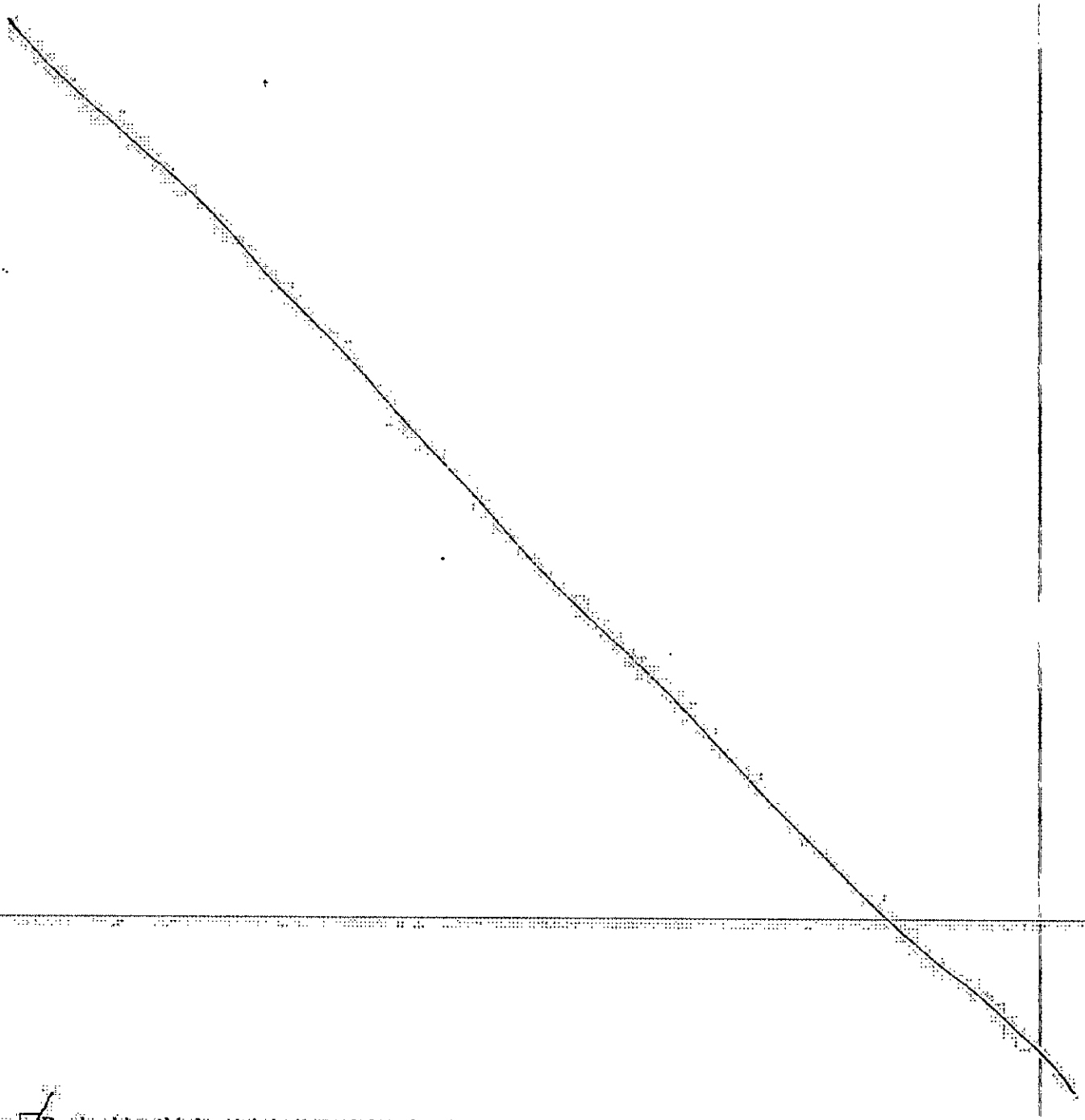

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: [signature] Date of Signature: 07 / 06 / 2022

Signature of Division Investigator: [signature] Date of Signature: 7 / 6 / 2022

Revised 9/2015

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH N/A	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Non-Resident	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Optum Infusion Services 308, LLC

Physical Address: 485 N Juniper Drive, Suite 2

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 480-705-6200 Toll Free # (NAC 639.708, NRS 639.23286): 888-705-4470

Fax: (844) 267-6202 Contact Email: orxpharmlic@optum.com

Website: https://www.optum.com/en/pharmacy-services.html

Nevada Business License # (if applicable) NV20243089039

Supervising/Managing Pharmacist Name (NRS 639.220): Shelby Botello

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20717

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Shelby Botello	NV Pharmacist Registration #: 20717
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona

Parent Company (if any): SCP Specialty Infusion, LLC

Corporation/Organization Name: Optum Infusion Services 308, LLC

Mailing Address: 485 N Juniper Drive, Suite 2

City: Chandler State: AZ Zip: 85226

Telephone: (832) 500-6226 Email: orxpharmlic@optum.com

Contact Person Name: Christine Feldman

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for Optum Infusion Services 308, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Kevin Burr
Print Name of Authorized Person

Kevin E. Burr
Original signature of Authorized Person (copies or stamps not accepted)

12-18-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Burr

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kevin E. Burr — 12-18-2024

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 12/30/24	Amount: $500-ck 1548058

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Optum Infusion Services 308, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 485 N Juniper Drive, Suite 2

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 480-705-6200 Toll Free # (NAC 639.708, NRS 639.23286): 888-705-4470

Fax: 844-267-6202 Contact Email: orxpharmlic@optum.com

Website: https://www.optum.com/en/pharmacy-services.html

Nevada Business License # (if applicable) NV20243089039

Supervising/Managing Pharmacist Name (NRS 639.220): Shelby Botello

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20717

Name of Designated Person(s) as defined by revised USP-797 guidelines: Shelby Botello

Email of Designated Person(s): shelby_botello@optum.com

Telephone of Designated Person(s): (480) 705-6200

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 12/07/2024

6. What is the frequency of the recertification for the ISO classified areas? Semiannual-every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Every 2 weeks

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

All starting ingredients are purchased as sterile and conventionally manufactured/FDA approved with a NDC number. No bulk or API products are used. Products include but not limited to: Acyclovir, amphotericin, ampicillin, ampicillin/sulbactam, azithromycin, aztreonam, caspofungin, cefazolin, cefepime, cefotaxime, cefotetan, cefoxitin, ceftazidime, ceftriaxone, cefuroxime, ceftaroline, clindamycin, colistimethate, daptomycin, dexamethasone, diphenhydramine, ertapenem, famotidine, ganciclovir, gentamicin, hydrocortisone, imipenem/cilastatin, meropenem, methylprednisolone, micafungin, nafcillin, oxacillin, penicillin G, pantoprazole, piperacillin/tazobactam, ticarillin/clavulanate, tobramicin, vancomycin, voriconazole, deferoxamine, levofloxacin, blinatumomab, fluconazole, fluorouracil, posaconazole.
Parenteral Nutrition
Inotrope:Milrinone, Dobutamine
Hydration: Custom with electrolytes not commercially available as ordered by MD.

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Ste 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 405-271-1144

13. What is your procedure for visual inspection of compounded sterile products?

At the completion of a sterile compounding session and prior to releasing the CSP, the pharmacist will complete the following checks: a. Visually inspect each compounded dose using a contrasting (black/white) background to determine whether the physical appearance of the CSP is as expected (e.g., free of visible particulate matter, discoloration, or other defects). b. Visually confirm that the CSP and its labeling match the prescription compounding workorder. c. Compare drug vials, amount used, and syringes used to make doses, verifying the items listed on the compounding work order, including drug vials, diluent, NDC numbers, lot numbers, expiration dates, and delivery devices were correctly used to make the sterile compound.

14. How often do you perform glove fingertip and medial fill testing? Every 6 months for each compounding staff member.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

New hires undergo a series of didactic training modules related to aseptic processing and the cleanroom suite, along with policy orientation and USP <797> and <800> review. Once didactic training is completed, the staff member receives training with an assigned trainer (AT) or designated person (DP) to complete a series of competency checks, beginning with handwashing and gowning/garbing, followed by GFT testing. Then the staff member receives further hands on training on cleaning the cleanroom suite. Hands on training of aseptic technique is performed in a classroom setting. Eventually the new hire will complete a media fill test, and upon successful completion of all competencies will then begin to perform non-hazardous sterile compounding. Hazardous compounding is later learned after non-hazardous is mastered. Ongoing training occurs with daily supervision and semi-annual media fill, GFT, and competency evaluations.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Daily cleaning the non-hazardous PEC and SEC (every day compounding occurs) is completed with sterile TB1-3300 RTU. Surfaces cleaned daily include 100% of the PEC interior, carts, pass through, door handles, sink, stools, floors, and high touch surfaces. The hazardous compounding room receives a daily clean with sterile Peridox RTU each day that compounding is performed, at a minimum each Tuesday and Friday. Peridox serves as the decontamination/deactivation/sporicidal agent. Once per month sterile Peridox RTU is substituted to serve as the sporicidal agent. During this clean, all surfaces inside all ISO classified areas (non-hazardous and hazardous) are cleaned, including ceiling, walls, all surfaces of all furniture and doors ect.
70% SIPA is used to remove cleaning agent residues, and is used on the deck and high touch surfaces in the ISO 5 between each order made.

17. Who performs the sterile compounding process at your facility?

Licensed and Certified pharmacy Technicians with oversight/supervision by Pharmacists.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Lawrence Moore, (Resident PIC), Ralph Nellas, PharmD, Wiliam Assibey, PharmD, Peter Calander, PharmD, BCSCP

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Insulated cooler boxes with frozen and/or ambient gel packs are used to produce USP refrigerated or controlled room temperature conditions as applicable during transit. Overnight shipping is utilized, and the packout materials, process and procedure have been validated for performance in various seasons.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class II type A2 Biological Safety Cabinet		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: OnGuard 2 CSTD by BBraun		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Waste Disposal in the Home

1. UHG employees are not permitted to transport any pharmaceutical or hazardous waste.

2. Pharmaceuticals delivered to the home or residence become the property of the homeowner/patient. Pharmaceutical waste generated during home treatment is "household waste" and is exempt from hazardous waste regulations.

3. Prior to disposal, personal identifiers (name, DOB, etc.) should be removed from medication containers or crossed out with a black permanent marker. Place all excess or unused medications into a black plastic bag and secure tightly with a tie. Place this bag in a second black plastic bag and secure tightly with a tie. Place the double bagged waste into the regular trash as close to garbage pickup time as possible

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Once the employee is fully trained and experienced with non-hazardous compounding, the employee takes additional HD specific didactic training modules followed by a hazardous garbing/GFT test, hazardous media fill, and 1 on 1 shadowing with an assigned trainer or designated person.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.) N/A

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel? N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? N/A ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A			
6. What is the frequency for using sporicidal agents? N/A			
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	N/A	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	N/A	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shelby Botello PharmD MA

Name of Person who Completed the Form

Acute Care Pharmacist

Title

Signature (~~copies~~ or stamps not accepted)

12/26/24

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

State of: Arizona

County of: Maricopa

The foregoing instrument was acknowledged before me 26th day of December, 2024

Alexa Rodriguez

Your Name Here, Notary Public

My Commission Expires April 05 2028

ALEXA RODRIGUEZ
Notary Public - Arizona
Maricopa County
Commission # 668183
My Commission Expires April 05, 2028

Arizona State Board of Pharmacy

Physical address: 1110 W. Washington Street Suite 260 Phoenix, AZ 85007; Mailing address: PO Box 18520 Phoenix, AZ 85005-8520
Telephone: 602-771-2727 Fax: 602-771-2749 Website: pharmacy.az.gov

NOTICE OF INSPECTION RIGHTS-PREMISES SUBJECT TO INSPECTION

DATE: 05/25/2023	**Permittee:** Optum Infusion Services #308, LLC.
COMPLIANCE OFFICER/INSPECTOR: Steve Haiber	**Permit #:** Y005288
ACCOMPANIED BY: Chirag Patel	**Address:** 485 N Juniper Drive. Ste 2. Chandler, AZ. 85226. NABP Blueprint Inspection.

1. This inspection is conducted under the authority of Arizona Revised Statutes (A.R.S.) §§32-1904(A), 32-1927.03(D), 32-1939(A), 32-1941(C), 32-1964(A), 36-2522(E), and 36-2523(C)).

2. The purpose of the inspection is to determine compliance with A.R.S. Title 32, Chapter 18; A.R.S. Title 36, Chapter 27; and Arizona Administrative Code (A.A.C.) Chapter 23, Title 4.

3. Fees for the inspection are: ■ Not applicable ☐ Authorized by: _____ as follows: _____

4. An authorized on-site representative of this facility may accompany the inspector(s) during the inspection of the premises except during any confidential interview.

5. You have the right to have on request copies of any original documents taken by the inspector(s) during the inspection in those cases where the agency has authority to take original documents.

6. You have the right to have on request a split of any samples taken during the inspection if the split of any samples would not prohibit an analysis from being conducted or render an analysis inconclusive.

7. You have the right to have on request copies of any analysis performed on samples taken during the inspection.

8. You have the right to have on request copies of any documents to be relied on to determine compliance with licensure or regulatory requirements if the agency is otherwise allowed by law to do so.

9. You have the right to have on request a detailed billing statement that provides reasonable specificity of the inspection or audit fees imposed pursuant to paragraph 3 of this subsection and that cites the statute or rule that authorizes the fees being charged.

10. Each person whose conversation is tape-recorded during the inspection will be informed that the conversation is being recorded.

11. Each person interviewed during the inspection will be informed that statements made by the person may be included in the report. Participation in an interview is voluntary unless the person is legally compelled to participate in the interview. Each person interviewed will be allowed twenty-four hours to review and revise any written witness statement drafted by the inspector(s) and on which the inspector(s) request the person's signature. The inspector(s) may not prohibit the person from having an attorney or expert in their field present during the interview to represent or advise the regulated person.

12. An inspector shall at the end of the inspection, offer to review with an authorized representative of the regulated person, the findings of the inspection and what agency actions the regulated person can expect.

13. An inspector may not take any adverse action, treat the person less favorably or draw any inference as a result of the person's decision to be represented by an attorney or advised by other experts in their field.

14. The information and documents provided to the inspector(s) as part of an investigation are confidential pursuant to A.R.S. § 32-1940. Information and documents provided to the inspector(s) as part of an inspection are not confidential with the exception of trade secrets and propriety and confidential information.

15. A new or amended compliance action arising from the inspection may not be filed against the regulated person more than four years after the date of the inspection.

16. If you have any questions regarding this inspection, you may contact: **Steve Haiber (623) 217-3332 shaiber@azpharmacy.gov**

17. You have the right to appeal a final decision of the Board if any administrative order is issued or other enforcement action is taken based on the results of this inspection. Administrative hearing rights are found in A.R.S. § 41-1092 et seq. Rights relating to appeal of a final agency decision are found in A.R.S. § 12-901 et seq.

18. If you have any questions regarding your right to appeal an enforcement action taken by the Board based on this inspection, you may contact: Jennifer Keonavong, Deputy Director at 602-771-2735, or Arizona Ombudsman-Citizens' Aide: 7878 N. 16th St. # 235, Phoenix, AZ 85020 602-277-7292 (email: ombuds@azoca.gov).

Upon entry onto the premises for this inspection, the Board inspector(s) identified above presented photo identification indicating they are Board employees, and reviewed with me the above Notice of Inspection Rights. I have read the disclosures above and am notified of my inspection and due process rights as listed above. I understand that while I have the right to decline to sign this form, the Board inspector(s) may nevertheless proceed with the inspection.

Signature and Title of Authorized Representative: _____ **Date:** 05/25/2023

☐ **By checking this box, the inspector(s) documents the refusal of the authorized representative to sign the Notice of Inspection Rights.** [Version 02.2023.01]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Optum Infusion Services 308, LLC

Pharmacy/Wholesaler License # (if applicable) Y005288

Physical Address 485 N Juniper Drive Ste 2

City Chandler State AZ Zip 85226

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 480-705-6200 Website https://www.optum.com/en/pharmacy-services.html

Licensing Company Email orxpharmlic@optum.com

Section 2: Personal Information

First Shelby Middle Taye Last Botello

Alias(es, nicknames, name changes, etc.) Greenwood (maiden name)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Phoenix State AZ [redacted]

Telephon[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Midwestern University Glendale			From - To (MM/YY – MM/YY): 08/16-05/20	
Address: 19555N. 59th Ave	City: Glendale		State: AZ	Zip: 85308
Diploma/Degree obtained, if any: Masters of Arts Biomedical Sciences / Doctor of Pharmacy (pharmD)				
School Name: Arizona State University			From - To (MM/YY – MM/YY): 08/2011-05/2014	
Address: 4701 W. Thunderbird Rd	City: Glendale		State: AZ	Zip: 85306
Diploma/Degree obtained, if any: Bachelors of Science - Life Sciences				
School Name: North Pointe Preparatory			From - To (MM/YY – MM/YY): 08/2007-05/2011	
Address: 10215 N. 43rd Avesteb	City: Phoenix		State: AZ	Zip: 85051
Diploma/Degree obtained, if any: Highschool Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20 - current	[redacted]	Phoenix	AZ	[redacted]
12/19 - 03/20		Carson City	NV	
05/2013 - 12/19		Peoria	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Optum Infusion Pharmacy			From - To (MM/YY – MM/YY): 10/22-present
Business Address: 485 N. Juniper Drive 2	City: Chandler	State: AZ	Zip: 85226
Phone: 480-705-6200	Title: Home infusion pharmacist		Number of Employed Hours: 4160+
Description of Duties: Dispense injectables, IV, enteral & related supplies as per state/federal requirements, compound meds using appropriate supplies, components, sterile environ. process & ship outgoing orders, review orders & clinicals verifying of Rx, Labs/kinetics enteral, parenteral nutrition neonates/peds/adults			
Business Name: PCI/Arizona Home Care			From - To (MM/YY – MM/YY): 03/20[illegible]-10/22
Business Address: 1624 S. Edward Dr	City: Tempe	State: AZ	Zip: 85281
Phone: 480-246-3975	Title: Home Infusion Pharmacist/Nuclear pharm		Number of Employed Hours: 3000 hrs
Description of Duties: Front-end-Prescription verification & dispensing, clinical review coordination of pharmacy SOC, kinetics, Lab review, clinical review/patient education. Back end-aseptic compounding according to USP 797 & USP 800 (nuclear). Nuclear: Automated user-verification of minimum Rx req for nuclear compounding, Aseptic comp			
Business Name: Walmart			From - To (MM/YY – MM/YY): 11/20-02/21
Business Address: 3770 US-395	City: Carson City	State: NV	Zip: 89705
Phone: 775-883-6535	Title: Staff Pharmacist		Number of Employed Hours: ~500 hours
Description of Duties: Provide pharmaceutical care to customers, support/manage pharmacy team, process & accurately dispense prescription orders, maintain pt confidentiality, document & maintain records esp those related to controlled substances			
Business Name: CVS Store #17463			From - To (MM/YY – MM/YY): 08/20-11/20
Business Address: 9955 S. Cotton Ln	City: Goodyear	State: AZ	Zip: 85338
Phone: 480-627-3276	Title: PRN Pharmacist		Number of Employed Hours: ~400 hours
Description of Duties: Lead/direct technician support staff, adopt & manage pt care plans, enter prescriptions, verify, clarify & dispense according to state Laws, educate pts & providers, record keeping according to state/federal Laws, dispense controlled substances, vaccinations			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	NA	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	X	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/26/24		AZ	Phoenix	Maricopa
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
CV2024-001628	Superior Court of State of Arizona			
Reason/Charge				
Claim for Posonal Property Dmg - existing Crack in wall				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Defendant		Arbitration		
Name of Business/Industry/Entity				
Mattox vs. Botello et al.				

Provide explanation below:

Our neighbor initiated litigation claiming personal property (Damage) Dmg for an existing crack in a burdary wall between our properties present prior to us taking ownership in an attempt to extort $15-000 from us through arbitration. on 09/19/24 the arbitrator found in favor of us (defendents) against the plaintiff & were awarded all atorney fees as the action was found to be prosecuted in bad faith. The plaintiff attempted to appeal the Judgement award and settled agreeing to dismiss the case with prejudice.

Original Signature (electronic, copies or stamps not accepted)

12/26/24
Date

I, Shelby Botollo, **certify that as the designated representative for**

Optum Infusion Services 308, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SB I am at least 21 years of age;
3. SB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Shelby Botollo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/26/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shelby Botello

Print Name (First, Last)

Original Signature (~~electronic~~ copies or stamps not accepted)

12/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Shelby Botello, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that ~~misrepresentation or failure to reveal~~ information requested may be deemed sufficient cause for denial or revocation ~~of the license, registration, permit, certificate~~ or certification for which I am applying for.

Original Signature

12/26/24

Date

Subscribed and Sworn to before me this 26th day of December.

Notary Public Signature

ALEXA RODRIGUEZ
Notary Public - Arizona
Maricopa County
Commission # 666183
My Commission Expires April 05, 2028

(Seal)

Peter H. Westby, Bar No. 003487
PLATT & WESTBY, P.C.
2916 North 7th Avenue, Suite 100
Phoenix, Arizona 85013
Telephone: 602-277-4441
courtemails@plattwestby.com
Arbitrator

IN THE SUPERIOR COURT OF MARICOPA COUNTY
IN AND FOR THE COUNTY OF MARICOPA

SHEILA MATTOX, Plaintiff, vs. ROBERT BOTELLO, et. al., Defendants.	Case No. CV2024-001628 **ARBITRATION AWARD**

This matter came for a mandatory arbitration hearing on September 19, 2024. Pursuant to the testimony presented, the Arbitrator finds in favor of Defendants, Shelby and Robert Botello ("Defendants") and against Plaintiff, Sheila Mattox ("Plaintiff"). Defendants are awarded attorneys' fees per A.R.S §12-349, in the amount of $11,247.00 and costs in the amount of $375.76, for a total judgment amount of $11,622.76, with interest accruing at the rate of 9.5% per annum until paid. Pursuant to A.R.S. §12-350, the Arbitrator finds that Plaintiff did not take available steps to determine the validity of her claim prior to filing suit; the action was prosecuted in bad faith; the action was groundless and Plaintiff was aware that her claims were groundless as testified during the arbitration hearing. The issues of fact determinative of the validity of Plaintiff's case were not reasonably in conflict; in fact Plaintiff's testimony stressed that the cause of the water damage to the Plaintiff's wall was unknown.

The arbitrator took the relative financial positions of all parties into consideration.

DATED THIS: October 8, 2024

PLATT & WESTBY, P.C.

Peter H. Westby, Esq.
Arbitrator

ORIGINAL of the foregoing filed this 8 day of October 2024 with the:

Clerk of the Superior Court
Maricopa County

COPY of the foregoing emailed this 8 day of October 2024 to:

Ginger Jean Mattox
[redacted]
Phoenix, Arizona [redacted]
Plaintiff Pro Per

Marteal Lamb
LAW OFFICE OF MARTEAL LAMB, PLC
2550 West Union Hills Drive, Suite 350
Phoenix, Arizona 85027
Attorney for Defendants

By

Clerk of the Superior Court
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LAW OFFICE OF MARTEAL LAMB, PLC
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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN THE COUNTY OF MARICOPA

201 W. JEFFERSON ST. PHOENIX AZ 85003

CASE#: CV2024-001628

SHEILA MATTOX,

Plaintiff,

(Civil)

vs.

ROBERT BOTELLO et al,

Defendant(s).

_____/

NOTICE OF SETTLEMENT

TO: THE COURT, THE CLERK OF THE COURT AND ALL PARTIES:

Defendants, by and through their undersigned counsel, advises the court that the parties have reached a settlement on the above-referenced matter. Plaintiff has signed a Stipulated Judgment to be signed and filed with the court. The parties request that the court vacate the pretrial scheduled for November 26th at 9:15am.

Doc ID: 64ff9cca5a091df6aeb4d360745e86735d398531

I understand and consent to the above.

Defendant Shelby Botello

Respectfully submitted,

Defendants Shelby and Robert Botello
By their attorney,

/s/ Marteal Lamb

MARTEAL LAMB
attorney reg. number 029486
LAW OFFICE OF MARTEAL LAMB LLC
2550 W UNION HILLS DR #350

PHOENIX, AZ 85027

Date: November 25, 2024

Doc ID: 64ff9cca5a091df6aeb4d360745e86735d398531

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was sent via electronic mail /facsimile on this November 25 , 2024 to Plaintiff via US Mail "Ginger" Sheila Mattox [redacted] Phoenix, AZ [redacted]

Respectfully Submitted,

LAW OFFICE OF MARTEAL LAMB, PLC

Dated: 11 /24

/s/Marteal Lamb

Marteal Lamb, Esq.

2550 W. Union Hills Dr., # 350

Phoenix, AZ 85027

Attorney for Defendants

Granted with Modifications
See eSignature page

Clerk of the Superior Court
*** Electronically Filed ***
L. Gilbert, Deputy
12/12/2024 8:00:00 AM
Filing ID 18996443

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN THE COUNTY OF MARICOPA

201 W. JEFFERSON ST. PHOENIX AZ 85003

CASE#: CV2024-001628

SHEILA MATTOX,

Plaintiff,

(Civil)

vs.

ROBERT BOTELLO et al,

Defendant(s).

_____/

ORDER DISMISSING COMPLAINT WITH PREJUDICE

Upon review of the Parties' Stipulation of Dismissal with Prejudice and for good cause appearing therefore, it is hereby SO ORDERED that the Complaint including all claims in the above-referenced case, are hereby DISMISSED WITH PREJUDICE. Each side is to bear its own costs and attorney's fees.

The Court retains jurisdiction of this matter for the purposes of taking any action needed to enforce the terms of the Stipulation of Dismissal with Prejudice, which is filed with the court.

SO ORDERED, this _____ day of December, 2024.

_____

Judge Randall Warner

eSignature Page 1 of 1

Filing ID: 18996443 Case Number: CV2024-001628
Original Filing ID: 18988818

Granted with Modifications

/S/ Randall Warner Date: 12/11/2024
Judicial Officer of Superior Court

ENDORSEMENT PAGE

CASE NUMBER: CV2024-001628

SIGNATURE DATE: 12/11/2024

E-FILING ID #: 18996443

FILED DATE: 12/12/2024 8:00:00 AM

MARTEAL D LAMB IV

GINGER SHEILA LMATTOX
[redacted] PHOENIX AZ [redacted]

National Association of Boards of Pharmacy®
Verified Pharmacy Program™ Inspection Form

1.00 General Pharmacy Inspection

Business or Corporation:	Optum Infusion Services 308, LLC			Day 1:	05-25-2023	Inspector(s) and Affiliation	
Doing Business As (DBA):				Start Time:	09:15	Steve Haiber	
Address:	485 N. Juniper Drive Suite 2			End Time:	17:45	Chirag Patel	
City:	Chandler			Day 2:			
State:	AZ	Zip Code:	85226	Start Time:			
Telephone number:	480-705-6200			End Time:			
Toll-Free number:	888-705-4470			Pharmacist-in-Charge	Lawrence Moore		
Fax number:	844-267-6200			PIC email	lmoore@optum.com		
Website:	specialty.optumrx.com			Nonsterile Compounding Manager	Pharmacy does not perform non-sterile compounding		

Hours of Operation *Please indicate in 24-hour format (military time)*

Sun	Mon	Tues	Wed	Thu	Fri	Sat
	8:00	8:00	8:00	8:00	8:00	
	17:00	17:00	17:00	17:00	17:00	

Sterile Compounding Manager	Ralph Nellas				
Hazardous Compounding Supervisor	Peter Calander				

		Y	N	Notes
2.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Y		
3.00	Are there any other businesses located at this address? *If so, note type of business and name.*	N		
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	Y		https://specialty.optum.com/
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If so, list.*	N		

6.00	Does the pharmacy allow patients to enter/update profile and medical information through the website?	N		
7.00	Are patients able to order or refill prescriptions through the website? *If so, describe.*	N		
8.00	Are photographs allowed during the inspection (no PHI)?	Y		
9.00	**List of additional personnel interviewed as part of the inspection:**			

10.00

List of personnel present at the time of the inspection. If more than 10, list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

	Name	Title	License or registration available and current		Name	Title	License or registration available and current
1	Lawrence Moore	Director of Pharmacy/PIC	S018197	6	2 - Technician Trainees		
2	Peter Calander	Pharmacist	S019262	7			
3	Mhd Baraa Alsasa	Sr. Pharmacy Technician Purchasing	T059290	8			
4	26 - Pharmacists			9			
5	42 - Technicians (certified)			10			

If more than 10, list the number/title (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks etc) for the additional personnel present.

11.00

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency:	License Type:	Business Name on License/Registration:	License/ Registration Number:	Expiration Date:	Frequency of renewal
AZ State Board of Pharmacy	Pharmacy LS	Optum Infusion Services, LLC	Y005288	10/31/2024	2 years
DEA	Controlled Substance Registration Certificate	Optum Infusion Services 308, LLC	FS2161343	12/31/2025	3 Years
Alaska Board of Pharmacy	Out-Of-State Pharmacy	Optum Infusion Services 308, LLC	202116	6/30/2024	2 Years
Hawaii Department Of Commerce and Consumer Affairs	Misc. Permit	Optum Infusion Services 308, LLC	PMP-1592	12/31/2023	2 years

	Inspector Notes:									

	Type(s) of practice Type "X" for all that apply				Facility Size in Square Feet and Number of PECs		Volume Dispensed		Personnel	
12.00	Traditional retail		Institutional		Total Pharmacy size:	68,345	**Total Prescriptions Dispensed/day:**	319	Total Pharmacists:	28
	Open to the Public		Long-Term Care		Nonsterile Compounding Room size:		% Veterinary Prescriptions		Number of Compounding Pharmacists	7
	Closed Door	X	HMO/PBM only		Nonsterile Compounding powder hoods number:		% Controlled Substance Prescriptions	0.4	Total Graduate Students or Residents:	
	Drive-through window		Internet Pharmacy		Nonsterile Hazardous Drugs (HD) Compounding Room size:		% Nonsterile Compounded Prescriptions		Total Student Interns:	
	Mail/Deliver (in state)	X	Telepharmacy		Nonsterile HD Compounding BSC/CACI hoods number:		% Sterile Compounded Prescriptions	20.7	Total Technicians:	45
	Mail/Deliver (out-of-state list below)	X	Central Fill/Processing/ Shared Services		Sterile Compounding Ante Room size:	A1 =122 A2 = 126	% Hazardous Drugs (HD) Prescriptions	0.18	Number of Compounding Technicians	11
	Veterinary Pharmacy		Specialty Pharmacy	X	Sterile Compounding Clean/Buffer Room size:	CR1=457 CR2=378	**Volume Distributed**		Of technicians, how many are certified?	43
	Investigational Drugs, Clinical Trials/Research		Handles Medical Marijuana		Sterile Compounding Number LAFW hoods/areas:	6	**Total Orders Distributed/day:**		Of technicians, how many are techs-in-training?	2
	Nuclear Pharmacy				Sterile Compounding Number BSC hoods:		Percent Veterinary		Total Other Licensed Personnel:	

Manufacturer		Wholesale Distributor		Sterile Compounding Number CAI/CACI hoods:		Percent Controlled Substances		Total Other Unlicensed Personnel:	5
Outsourcing Facility		Provide products for "Office Use"		Negative Pressure Sterile HD Room size:	174	Percent Nonsterile Compounded		Ratio #tech:#RPh present at time of inspection:	AZ has no ratio
Nonsterile Compounding		Nonsterile Hazardous Drug Compounding		Sterile HD Compounding Number of BSC hoods:	2	Percent Sterile Compounded		**Total Pharmacist Hours Per Week:**	
Sterile Compounding	X	Sterile Hazardous Drug Compounding	X	Sterile HD Compounding Number of CACI hoods:		Percent Hazardous Drugs		**Total Technician Hours Per Week:**	

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):

	State	Volume dispensed	/day, week	Volume DISTRIBUTED	/day, week		State	Volume dispensed	/day, week	Volume DISTRIBUTED	/day, week

	Types of Practice Additional Questions If any part of a question is no, enter "N" and explain the observation.	Y	N	?	NA	Notes
13.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If so, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Y				Limited shipment of a patient specific biological drug to practitioner office for administration to the patient.
14.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If so, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*		N			
15.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?		N			
15.01	If so, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*					
15.02	If so, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*					

	General Operations and Licensure If any part of a question is no, enter "N" and explain the observation.	Y	N	?	NA	Notes

16.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *Provide details if "no", such as closed-door pharmacy.*		N			Closed door facility. Licenses & permits posted and visible for in-house VIP tours.
17.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Y				
18.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*		N			No violations issued.
19.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above.*		N			
20.00	Has this pharmacy been inspected by any other state for which it holds a license? *If so, note the state and the date of the inspection and frequency of inspections by other states.*		N			
21.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the exemption or restriction.*		N			
22.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the waiver or variance.*		N			
23.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If so, note the agency and additional item.*		N			
24.00	Has the pharmacy been inspected by the DEA? *If so, indicate the inspection date and note any deficiencies. Also note how frequently the pharmacy is inspected by the DEA.*		N			
25.00	Has the pharmacy been inspected by the FDA? *If so, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	Y				No for the current location. Yes for the firm's former location which was inspected by the FDA on 03/08/2022.

26.00	Does the pharmacy hold any accreditations or certifications? *If so, indicate which in notes.*		Y				URAC & ACHC
27.00	Has the pharmacy held any accreditations or certifications in the past that have been rescinded or suspended? *Provide a list and the reasons for discontinuation.*			N			
28.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *If so, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed. Verify that the lab director is current (usually the PIC is the lab director named).*			N			
29.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *How long are records kept? If not on site, where?*		Y				Maintained electronically for at least 7 years
29.01		Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how they are accessed.*	Y				Written prescriptions received via fax or electronic process. Verbal orders are typed directly into an electronic template. All records are maintained electronically.
29.02		Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Note if they are kept electronically or printed and kept in hard copy, and if off site: how they are accessed.*	Y				Maintained electronically for at least 7 years
29.03		Are all dispensing records (refills, verifications, DUR overrides, kept on site for the entire retention period? *Note if they are kept electronically or printed and kept in hard copy, and if off site: how they are accessed.*	Y				Records on site are from April 1st to present. Documents are also stored at Iron Mtn from 01/01/ 2018 to 03/31/2023. Further, all documents are readily retrievable from electronic record.

Personnel **If any part of a question is no, enter "N" and explain the observation.**		**Y**	**N**	**?**	**NA**	**Notes**
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *How is this documented?*	Y				A copy of the license for each licensee is maintained w/in a 3 ring binder for inspection.
31.00	Is there a process for periodic verification of validity of licenses? *Describe.*	Y				Firm's HR department obtains a license and confirms license status via the AZ state board of pharmacy website. Confirmation process also takes place with every 2 year license renewal.

32.00	Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? *Are the certifications current? (Immunization, CPR, MTM, etc.)*	Y				
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*				NA	AZ does not require a tech to pharmacist ratio

	Facility and Security If any part of a question is no, enter "N" and explain the observation.	Y	N	?	NA	Notes
34.00	Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state?	Y				Pharmacy has a working security / alarm system
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*		N			Facility does not handle C2 drug at this time. Facility does maintain a secure cabinet with a combination keypad code to allow pharmacist access.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *How will the drug products be handled?*	Y				Firm would deploy pharmacist to remain on site until perimeter security was restablished.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked.*	Y				Facility is new. Permit issued 3/31/2023. Walk thru of facility indicates clean, organized operation.
37.01	Does the pharmacy destroy prescription products on site (such as expired, damaged, recalled, etc) and appropriately document the destruction? *View destruction logs.*	Y				All wasted product is documented. On site destruction would be limited to non-hazardous non drug products such as normal saline, sterile water.
37.02	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *Indicate name of reverse distributor used, if applicable.*	Y				Pharmalink, Inc.
37.03	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *Indicate how often the bin is emptied/collected and the vendor used.*	Y				Facility maintains specific containers dedicated for bulk waste and trace chemo waste. Hazardous waste is held for return to Veolia.

38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*		N			Closed door facility. If a patient were to arrive at the pharmacy to pick up an order a pharmacist would perform counseling in a private office area.
39.00	Is temperature in the drug storage area monitored? *Describe the process and if it is manual, mechanical, or electronic. Indicate range. How are excursions detected? How long are records maintained?*	Y				Electronic documentation maintained. Accessible on line. Retension maintained for at least 2 years.
39.01	Is the temperature in the drug storage area within the USP range for controlled room temperature (20°-25°C or 68°-77 °F)? *Record the temperature at the time of inspection.*	Y				Drug storage area temps: warehouse = +71.35F, pharmacy prep west = +69.65F, pharmacy prep east = + 69.5F,
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Y				
41.00	The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7. *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Y				OOS events - mgmt is notified via email and text alerts. Alarm triggered when temperature ready is above or below +68 - +77F for greater than 60 minutes.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F)? *Record the temperature of the refrigerator at the time of inspection.*	Y				Walk in refrigator south = +40.1F, Walk in refrigerator north = +41F
42.00	The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7. *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Y				OOS events - mgmt is notified via email and text alerts. Alarm triggered when temperature ready is above or below+36 to +46F for greater than 60 minutes.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F)? *Record the temperature of the freezer at the time of inspection.*	Y				Freezer units only maintained for gel bricks. No drug product stored.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe processes*	Y				Back up generator available to supply power to the refrigeration/freezer units. Product would be relocated to another refrigerator unit in the event of a compressor failure.

44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Y				Back up generator available to supply power to the facility in the event of a power failure. 40 separate HVAC units available to provide backup temperture control in the event of a compressor failure.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Y				Product exposed to excessive excursion would be destroyed.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Y				Facility utilizes repeater pumps and Exactamix 2400 for TPN's.

	Product Receipt and Inventory If any part of a question is no, enter "N" and explain the observation.	Y	N	?	NA	Notes
47.00	Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers? *Indicate who approves suppliers.*	Y				New vendor approvals performed by corporate purchasing department.
47.01	If the pharmacy is not restricted to vendors approved by the corporate office, or the pharmacy can purchase from other sources, are the other sources verified? *How?*		N			
47.02	Are all products received from authorized trading partners? *List trading partners.*	Y				McKesson, Cardinal, Baxter, Takeda, Fresenius
47.03	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received? *Explain procedure if transaction data not received.*	Y				Invoices received with the delivery or electronically. Shipments received without an invoice, bill of lading or packing slip are set aside until the appropriate documentation is received to validate the order.
47.04	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Y				
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *Who on the staff has the authority (Power of Attorney) to sign the DEA-222 forms?*		N			Facility does not handle C2 drugs at this time. Facility returned DEA 222 forms with former address to the DEA. Facility has not ordered new 222 forms for the new facility address.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances?		N			Facility does not handle C2 drugs at this time. Facility returned DEA 222 forms with former
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*				N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Y				

52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Y				
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe.*		N			
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc)*	Y				On hand count changes limited to inventory team. On hand count changes reviewed by the inventory team of 3 employees . Investigation opened to review suspicious changes. Waste log maintained.
54.01	Are incidents of diversion or resignation/termination of personnel for cause appropriately reported? *Indicate agencies/law enforcement to whom reports are made.*		N			Division event would be reported to corporate security, DEA (if CS drug), AZ board of pharmacy and local law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?				N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*				N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Y				Most recent CSI conducted on 5/01/2023 at close.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Y				Change of PIC inventory performed 4/21/2023.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? *If so, indicate if the sale is recorded electronically or manually in a logbook.*		N			
58.01	Are these products mailed, sent, or delivered into other states? *View logs.*					
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *Indicate product types.*		N			
59.01	Are these products mailed, sent, or delivered into other states? *View logs.*					

60.00	Are outdated, damaged, or recalled products segregated? *How often does the pharmacy check for out-of-date products? Does it include OTC products?*		Y				Monthly report to identify short dated product.
60.01		If the pharmacy destroys products on site, are appropriate records kept of the destruction?	Y				
60.02		Does the pharmacy use a reverse distributor? *If so, indicate name of reverse distributor used.*	Y				Pharmalink, Inc.
61.00	Does the pharmacy **repackage** bulk containers of prescription medications into smaller containers for ease of use? *What expiration date is used on the repacked container?*		Y				Repackaging performed for dextrose reduction from manufacturer bag into elastomeric containter. With the exception of a minibag plus attachment a maximum 9 day BUD used.
62.00	Does the pharmacy **prepack** bulk containers of prescription medications into unit-of-use quantities? *What expiration date is on the prepacked containers?*			N			
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up? *Indicate if the products are returned to the bulk stock bottle or set on the shelf with the prescription label (with PHI obscured).*		Y				If labeled product returned to stock then all PHI removed prior to restocking. Original BUD is maintained.

Prescription Processing **If any part of a question is no, enter "N" and explain the observation.**			Y	N	?	NA	**Notes**
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system.*		Y				Profiling is performed by the firm's intake team.
64.01		If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *How is it indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*		N			
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*		Y				All prescriptions received are for previously profiled patients and prescribers.

65.01		Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Y				Should the pharmacist have a question as to the legitimacy of the prescription, such as suspected forgery, fraudulent prescription, stolen prescription, etc., the following will occur: i. Contact the prescriber or the prescriber's office or place of employment if there is a phone number on the face of the prescription or facsimile. ii. Verify the legitimacy of the prescription using online prescriber verification websites such as MediRegs. iii. Utilize online controlled substance usage tools such as PMP reporting sites. If the pharmacist questions the validity of the prescription, they have the right to refuse to fill the prescription.
65.02		Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*				N/A	Covid pandemic has resulted in a temporary relaxation of the face to face prescriber visit via the PREP act.
65.03		Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Y				E-Rx software supports both legend and CS prescription order receipt.
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*		Y				Multi step pharmacist verification process. At a minimum 4 separate pharmacist checks - OE review, 2nd OE review, review of compounding components used, pre-packing review.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *At what point in the process does the DUR take place?*		Y				DUR occurs after order entry.

67.01		Does the DUR include: • drug-drug interaction (Prescription and OTC) • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse) • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Y				Firm sets the fulfillment software system DUR alert level.
67.02		Does the pharmacy staff obtain additional information to use in the DUR process? *Describe.*	Y				SOP maintained to guide pharmacist DUR review process.
67.03		Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Y				
67.04		Does the pharmacy report appropriate data to the state PMP (in this state and the other states in which the pharmacy is licensed)?	Y				
67.05		Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Y				
67.06		Are DUR overrides/bypasses documented? Indicate if documented via a password/biometric override or by computer logs.	Y				
67.07		Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	Y				Medispan
67.08		If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed				N/A	

67.09		If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*				N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*		Y				Multi step pharmacist verification process. At a minimum 4 separate pharmacist checks - OE review, 2nd OE review, review of compounding components used, pre-packing review. / Documentation maintained w/in pharmacy system
69.00	Are filled prescriptions appropriately labeled?		Y				
70.00	**Confidentiality:** Is access to the pharmacy computer system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*		Y				CPR plus
70.01		Does the pharmacy appropriately destroy PHI including labeled prescription vials?	Y				
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?		Y				Overnight shipment
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: If the facility indicates "no", please ask each question below to verify.***		Y				
72.01		Is patient information (demographics and contact information) and profile information (allergies, disease states, etc) entered into the computer at another location?	Y				Non-licensed ancillary staff enter demographic information - pt name, address, insurance information / allergies, disease state information entered by a licensed nurse from a remote location under shared services rule.
72.02		Are prescriptions received by another location (including written, telephone, fax, electronic)?		N			

72.03		Is prescription information entered into the computer system at another location?	Y				Remote workers perform their activities from their residence.
72.04		Is the accuracy of the prescription information entered into the computer verified at another location?	Y				Remotely deployed pharmacist may perform order entry review from home.
72.05		Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?	Y				Remotely deployed pharmacist may perform DUR review from home.
72.06		Are any prescriptions dispensed or sold from this facility filled at another location? *If so, explain how the prescriptions are labeled including any identifier indicating it was filled at the other location.*		N			
72.07		If any of the above functions are performed at another location, is the other location under common ownership? *If not commonly owned, explain if there is a central fill or other agreement in place.*		N			
72.08		If any of the above functions are performed at another location, is that location in a different state than this facility? *If so, explain.*	Y				Pharmacists working remotely from another state who are licensed in the state of Arizona will process refills for patients.
72.09		If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?	Y				All records are stored electronically and are readily retrievable.
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*			N			
73.01		Do the emergency kits contain any compounded sterile products? If so, list.					
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*			N			

74.01		If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*					
74.02		Do the automated dispensing devices contain any compounded sterile products? If so, list.					

Patient Counseling and Communication **If any part of a question is no, enter "N" and explain the observation.**			**Y**	**N**	**?**	**NA**	**Notes**
75.00		Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	**Y**				Closed door pharmacy. Pharmacist available to provide face to face counsel in the event of a walk in patient pick up.
75.01		Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*				**N/A**	
76.00		Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?		**N**			Counsel on refill presriptions is not required.
76.01		Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*				**N/A**	
77.00		Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	**Y**				Closed door pharmacy. Pharmacist available to provide face to face counsel in the event of a walk in patient pick up.
77.01		Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*				**N/A**	
78.00		Is patient counseling provided for delivered prescriptions? *How? Printed information sent to patient, 800 number for patients to call, pharmacist calls patients directly, etc?*	**Y**				Printed written drug informaition provided with each order / Proactive pharmacist call to patient prior to shipment.
79.00		Is patient counseling provided for mailed prescriptions? *How? Printed information sent to patient, 800 number for patients to call, pharmacist calls patients directly, etc?*	**Y**				Printed written drug informaition provided with each order / Proactive pharmacist call to patient prior to shipment.

80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *How?*					N/A	
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *How?*			Y			FDA medication guide generated by CPR plus system.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn)*			Y			Rems programs that support the following drugs Ultomiris and Soliris
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *How? Describe.*			Y			Documentated w/in the patient's chart w/in CPR plus system.
84.00	Do patients have 24-hour access to a pharmacist? *How? Note: may not be required by the resident state.*			Y			After hours on call pharmacist available via toll free number
85.00	Are processes in place to handle a drug recall?			Y			
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?					N/A	
86.01		Does the take-back program include controlled substances?					
86.02		Does the pharmacy have a modified DEA registration for controlled substance take-back? *If so, list.*					

Quality Assurance/Quality Improvement Program If any part of a question is no, enter "N" and explain the observation.			Y	N	?	NA	Notes
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *Who oversees the program?*		Y				Quality related event documented within Atlas system. Process managed by
87.01		Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Y				SOP maintained in an electronic format. Accessible for all employees.
87.02		"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Y				Reviewed potential QRE trigger events with management - process aligns with the events listed in 87.02.
87.03		There is documentation of intitial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes.	Y				Documented w/in the Atlas pharmacy fulfillment system.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*		Y				Documentation required w/in 24 hours of the event discovery.

88.01		Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Y				Communicated in a weekly pharmacist and technician meetings.
88.02		Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Y				
88.03		Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicianss on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Y				
88.04		Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Y				
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*		Y				GM and PIC responsible. Monthly process improvement review. Quality dept puts together summary report which is reviewed by GM and PIC.
89.01		The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Y				Process review to identify process improvements to propose changes to upper management.
89.02		For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.		N			
90.00	**Quality meetings** are held at least annually by staff members of the Pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.		Y				Meeting held monthly.
90.01		The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Y				GM and PIC responsible. Monthly process improvement review. Quality dept puts together summary report which is reviewed by GM and PIC.

90.02		Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Y				GM and PIC responsible. Monthly process improvement review. Quality dept puts together summary report which is reviewed by GM and PIC.
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*		Y				Reported to FDA or product manufacturer
91.01		Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Y				Reported to FDA or product manufacturer
91.02		Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Y				Cority - internal reporting process for DME product events.
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.		Y				Internal audits performed with on-site pharmacist observation of compounding technician gowning and compounding processes.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.		Y				Consumer surveys performed on an ongoing basis. Results reviewed monthly.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.		Y				Complaints are documented within the firm's Atlas event system.

National Association of Boards of Pharmacy®
Verified Pharmacy Program™ Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

Business or Corporation:	Optum Infusion Services 308, LLC			Day 1:	05-25-2023	Inspector(s) and Affiliation
Doing Business As (DBA):	0			Start Time:	09:15	Steve Haiber
Address:	485 N. Juniper Drive Suite 2			End Time:	17:45	Chirag Patel
City:	Chandler			Day 2:	0	0
State:	AZ	Zip Code:	85226	Start Time:	0	0
Telephone number:	480-705-6200			End Time:	0	0
Toll free number:	888-705-4470			Pharmacist in Charge	Lawrence Moore	
Fax number:	844-267-6200			PIC e-mail	lmoore@optum.com	
Website:	specialty.optumrx.com			Nonsterile Compounding Manager	Pharmacy does not perform non-sterile compounding	

Hours of Operation						
Please indicate in 24 hour format (military time)						
Sun	Mon	Tues	Wed	Thu	Fri	Sat
0	8:00	8:00	8:00	8:00	8:00	0
0	17:00	17:00	17:00	17:00	17:00	0

Sterile Compounding Manager	Ralph Nellas					
Hazardous Compounding Supervisor	Peter Calander					

	General Operations and Information	Y	N	?	NA	Notes
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?				NA	Inspected pharmacy does not perform any non-sterile compounding activity therefore nonsterile CPD inspection was not performed

1.01		Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*				NA	
1.02		The compounded prescription produces a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.				NA	
1.03		Are nonsterile compounded prescriptions picked up at the pharmacy?				NA	
1.04		Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?				NA	
1.05		Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?				NA	
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*					NA	
2.01		Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?				NA	
2.02		Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?				NA	
2.03		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*				NA	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?					NA	
3.01		If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?				NA	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Indicate which in notes*					NA	
5.00	Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Indicate which in notes*					NA	

6.00	Does the pharmacy compound vitamin or nutritional supplements?					NA	
7.00	Does the pharmacy compound investigational drugs? *If so, provide list.*					NA	
8.00	Does the pharmacy make a copy of an approved commercial product? *Indicate volume or percent compounded currently in note.*					NA	
8.01	Products are verified as not available via FDA list and/or the manufacturer and documented					NA	
8.02	FDA list is monitored (and manufacturer) and when item is taken off the list or becomes available, any remaining stock is quarantined for destruction and not dispensed or distributed					NA	
9.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding in Notes* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.					NA	
10.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding in Notes* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available.					NA	
11.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding in Notes* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.					NA	
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous nonsterile compounding in Notes* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.					NA	
12.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?					NA	

12.02		Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, hazardous drug compounding waste. *Indicate how often the bin is emptied/collected and the vendor used.*				NA	
12.03		Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?				NA	
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*					NA	
14.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding in Notes*					NA	
15.00	**APIs:** Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?					NA	
15.01		Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*				NA	
15.02		Does the pharmacy verify that the source of the API is an FDA-registered facility? *How?*				NA	
15.03		Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources*				NA	
15.04		Does the computer track on-hand quantities of APIs used for compounding?				NA	
16.00	Does the pharmacy have its own lab to perform testing? *If so, what tests are performed in house?*					NA	
17.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*					NA	

18.00		**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? • QREs related to the preparation of compounded products • Personnel testing and validation • Equipment calibration, testing and validation • End product testing (such as: potency, particulates, consistency, etc.) • Patient or prescriber reports or complaints regarding nonsterile compounded products.				NA	
18.01		Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?				NA	
18.02		Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?				NA	
18.03		Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?				NA	

Component Selection and Use			Compliant	Non-Compliant	Unknown	N/A
19.00		**APIs**: Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*				NA
19.01		USP- or NF-grade substances used, if available				NA
19.02		If compendial quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.				NA
19.03		APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe in notes below if found. Request copies of the invoices for products with questionable labels.*				NA

19.04		If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding				NA
19.05		All substances and components have a complete label including a batch control or lot number, and an expiration date.				NA
19.06		For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*				NA
19.07		All APIs are labeled with the date they were received.				NA
19.08		If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.				NA
19.09		Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).				NA
19.10		Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation? That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.				NA
20.00	Where water is an ingredient, purified or distilled water is used.					NA
21.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.					NA
22.00	There are no preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).					NA
23.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.					NA
24.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.					NA
24.01		The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.				NA
24.02		It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.				NA
24.03		The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.				NA

24.04		The facility has a list of drugs and components not allowed when compounding for food-producing animals.					NA
24.05		The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					NA
Notes (refer to question number above)							

Beyond Use Dating (BUD)		Compliant	Non-Compliant	Unknown	N/A
25.00	BUDs are assigned from the day of preparation.				
26.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.				
27.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).				
28.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.				
29.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.				
30.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*				
Notes (refer to question number above)					

Environment		Compliant	Non-Compliant	Unknown	N/A
31.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.				NA
32.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.				NA

33.00	Only one preparation compounded at a time.					NA
34.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.					NA
35.00	The compounding area is well lit.					NA
36.00	The pharmacy performs **hazardous** non-sterile compounding a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*					NA
36.01		Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.				NA
36.02		Hood prefilters are checked and replaced regularly.				NA
36.03		If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.				NA
37.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available including appropriate PPE for hazardous drug compounding, if hazardous drugs are used.					NA
38.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.					NA
39.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended**)*					NA
40.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.					NA
41.00	**Temperature** in the compounding area is maintained to provide controlled room temperature storage of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.					NA
41.01		Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.				NA
41.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.				NA
41.03		Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas).				NA
42.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.					NA
42.01		Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.				NA

42.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.				NA
42.03		Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).				NA
43.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.					NA
44.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.					NA
45.00	All components and packaging containers and closures are properly rotated to use oldest first.					NA
46.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)					NA
47.00	Trash is disposed of in a safe, sanitary, and timely manner including hazardous waste.					NA
48.00	**Recommended:** Environmental testing is performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? *Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials, not using a hood, or the compounding room not segregated.*					
Notes (refer to question number above)						

Training		**Compliant**	**Non-Compliant**	**Unknown**	**N/A**
49.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.				NA
50.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.				NA
51.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.				NA

52.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting*				NA
53.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually (including hazardous drug handling).				NA
54.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.				NA
Notes (refer to question number above)					

Compounding Equipment		Compliant	Non-Compliant	Unknown	N/A
55.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*				NA
56.00	Scales, balances, or other equipment used for measurement is validated and calibrated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.*				NA
57.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. Hood filters are checked regularly and replaced when necessary.				NA
58.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*				NA
59.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.				NA
Notes (refer to question number above)					

	Compliant

Documentation				Non-Compliant	Unknown	N/A
60.00	The pharmacy creates a master formulation record the first time before compounding a new preparation					NA
60.01		Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.				NA
60.02		The master formulation record contains: 1. Official or assigned name, strength, and dosage form 2. All necessary calculations 3. Description of all ingredients and their quantities 4. Compatibility and stability information including references (when available) 5. Equipment used for the preparation 6. Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) 7. Container used and packaging requirements 8. Assigned BUD information 9. Labeling information including the name of and quantity or concentration of each active ingredient 10. Description of the finished preparation 11. Storage requirements 12. Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).				NA
61.00	The pharmacy creates a compounding record for each compound prepared					NA
61.01		The compounding record includes: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Person compounding the preparation 6. Person performing the quality control procedures 7. Person who approved the preparation 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Description of the final preparation 11. Assigned BUD 12. Duplicate label 13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate				NA

Notes (refer to question number above)

	Compounding Procedures	Compliant	Non-Compliant	Unknown	N/A
62.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.				NA
63.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.				NA
64.00	The containers and closures selected meet USP standards (from container supplier).				NA
65.00	Container selection determined by physical and chemical properties of the preparation.				NA
66.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.				NA
67.00	Personnel don appropriate protective garb when performing compounding including hazardous compounding.				NA
68.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*				NA
69.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*				NA
70.00	If there are any deviations from the master formulation record, these deviations are recorded.				NA
71.00	There is a plan for cleaning. *After each preparation, daily tasks, monthly tasks, etc.*				NA
72.00	Personnel are appropriately garbed for protection when cleaning.				NA
	Notes (refer to question number above)				

Finished Preparation Release Checks and Tests			Compliant	Non-Compliant	Unknown	N/A
73.00	The finished preparation is observed to appear as expected in the master formulation record and documented.					NA
74.00	As appropriate, the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength and is documented.					NA
75.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.					NA
76.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.					NA
76.01		If any failed tests or discrepancies are observed, there an investigation and appropriate corrective actions taken before dispensing to patient				NA
76.02		If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.				NA
77.00	There are appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Validation of equipment and personnel performance documentation*					NA
78.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.					NA
79.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).					NA
80.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.					NA
81.00	Preparations are stored properly prior to dispensing based upon conditions upon which BUD was assigned.					NA
82.00	Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability.					NA

Notes (refer to question number above)

Patient Counseling and Communication		Compliant	Non-Compliant	Unknown	N/A
83.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?				NA
84.00	Compounding pharmacies: Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products? How?				NA
85.00	Compounding pharmacies: Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?				NA
86.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.				NA
Notes (refer to question number above)					

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

National Association of Boards of Pharmacy®
Verified Pharmacy Program™ Inspection Form

Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

Business or Corporation:	Optum Infusion Services 308, LLC			Day 1:	05-25-2023	Inspector(s) and Affiliation
Doing Business As (DBA):	0			Start Time:	09:15	Steve Haiber
Address:	485 N. Juniper Drive Suite 2			End Time:	17:45	Chirag Patel
City:	Chandler			Day 2:	0	0
State:	AZ	Zip Code:	85226	Start Time:	0	0
Telephone number:	480-705-6200			End Time:	0	0
Toll free number:	888-705-4470			Pharmacist in Charge	Lawrence Moore	
Fax number:	844-267-6200			PIC e-mail	lmoore@optum.com	
Website:	specialty.optumrx.com			Nonsterile Compounding Manager	Pharmacy does not perform non-sterile compounding	

Hours of Operation	*Please indicate in 24 hour format (military time)*					
Sun	Mon	Tues	Wed	Thu	Fri	Sat
0	8:00	8:00	8:00	8:00	8:00	0
0	17:00	17:00	17:00	17:00	17:00	0

Sterile Compounding Manager	Ralph Nellas
Hazardous Compounding Supervisor	Peter Calander

Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. (*NA if no sample)*

General Operations Information	Y	N	?	NA	Notes

1.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?		Y				
1.01		Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	Y				
1.02		Are sterile compounded prescriptions picked up at the pharmacy?	Y				Close door pharmacy - pharmacist available to dispense to any walk up patients..
1.03		Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	Y				
1.04		Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Y				Sterile compounded prescriptions can be delivered to the practitioner for administration to the patient. This is practice that occurs very seldom.
2.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*			N			
2.01		Does the pharmacy distribute sterile compounded preparations to practitioners for office use?					
2.02		Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?					
2.03		Is the pharmacy registered with the FDA as an Outsourcing Facility?					
2.04		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*					
3.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?			N			
3.01		If so, does the pharmacy have central fill contracts or agreements with these pharmacies for patient specific preparations?					
4.00	Which of the following types of sterile compounds does the pharmacy prepare?						
4.01		Allergen extracts		N			
4.02		Parenteral solutions	Y				
4.03		Parenteral *suspensions*	Y				TPN

4.04		Preservative-free parenterals	Y				
4.05		Ophthalmic preparations		N			
4.06		Oral or nasal *inhalation* preparations (not topical sprays)		N			
4.07		Baths and soaks for live organs and tissues		N			
4.08		Irrigations for wounds and body cavities	Y				Bladder irrigations
4.09		Any other sterile preparations (implants, pellets, etc.) *List in Notes.*		N			
5.00	Does the pharmacy compound investigational drugs? *If so, provide list.*			N			
6.00	Does the pharmacy make a copy of an approved commercial product? *Indicate volume/percent compounded currently in Notes .*			N			
6.01		Products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.					
6.02		The Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing.					
6.03		If the essential copy is not on the Drug Shortage List, the compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner					
7.00	Does the pharmacy perform **low-risk** compounding? *Indicate percentage of low-risk sterile compounding in Notes*		Y				
7.01		Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*	Y				Company SOP limits BUD to 9 day maximum.
8.00	Does the pharmacy perform **medium-risk** compounding? *Indicate percentage of medium-risk sterile compounding in Notes*		Y				
8.01		Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*	Y				Company SOP limits BUD to 9 day maximum.

9.00	Does the pharmacy perform **high-risk** compounding? *Indicate percentage of high-risk sterile compounding in Notes*			N			
9.01		Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)? *If no, indicate maximum BUD assigned in Notes.*					
10.00	Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?			N			
10.01		Are BUDs assigned to include the full length of time during which the CSP will be administered or present in the reservoir of the pump? *If not, indicate in "Notes" the maximum length of time of administration that may be beyond the BUD assigned*					
11.00	Does the pharmacy perform compounding for **immediate use?** *Indicate percentage of immediate use sterile compounding in Notes*			N			
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding in Notes*			N			Facility has the capability to perform USP 800 compounding, but has not performed any hazardous compounding activity.
12.01		Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Y				
12.02		Are hazardous drugs segregated and stored in a room that is negative pressure (at least 0.01" wc) to adjacent areas and with at least 12 ACPH?	Y				
12.03		Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?	Y				
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*		Y				Paper and electronic version maintained and accessible by employees.
14.00	Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*			N			

15.00	Does the pharmacy compound using any Federally **controlled substances I-V**? *Indicate controlled substances used and percentage of controlled substance sterile compounding in Notes*		Y				Diazepam & lorazepam / 0.2 %
16.00	**APIs:** Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?			N			
16.01		Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*					
16.02		Does the pharmacy verify that the source of the API is an FDA-registered facility? *How?*					
16.03		Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources*					
16.04		Does the computer track on-hand quantities of APIs used for compounding?					
17.00	Does the pharmacy have a **lyophilizer**?			N			
17.01		Where is the lyophilizer located? *Indicate ISO class of room.*					
17.02		Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer					
17.03		Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?					
18.00	Does the pharmacy have its own lab to perform testing? *If so, what tests are performed in house?*			N			
19.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*		Y				ARL / annual sterility & potency test performed for each compounding technician

20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include sterile compounding measures? • QREs related to the preparation of compounded products • Nonviable environmental monitoring and testing • Viable environmental testing • Personnel testing and validation • Equipment calibration, testing and validation • Sterilization method testing and validation • End product testing (such as: potency, particulates, sterility, endotoxin, etc.) • Patient or prescriber reports or complaints regarding CSPs		Y				
20.01		Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Y				
20.02		Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	Y				
20.03		Are QREs involving CSPs that may have been contaminated or are recalled reported to the Board of Pharmacy?				**N/A**	
20.04		Are all incidents (CFUs detected by any personnel, environmental, or product testing; or any other checks or tests includind endotoxin, purity, potency, etc.) remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future?	Y				

Component Selection and Use			Compliant	Non-Compliant	Unknown	N/A
21.00		**APIs**: Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*				X
21.01		USP- or NF-grade substances used				
21.02		Drug products without a USP monograph are componenets of an FDA-approved drug.				
21.03		Drug products without a USP monograph, that are NOT componenets of an FDA-approved drug are on a list developed by FDA				
21.04		APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. Photograph and describe in notes below if found. Request copies of the invoices for products with questionable labels.				
21.05		If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding				
21.06		All substances and components have a complete label including a batch control or lot number, and an expiration date.				
21.07		For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than three (3) years, is supported with data and/or testing.				
21.08		All APIs are labeled with the date they were received.				
21.09		If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.				
21.10		Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).				
21.11		Components from foreign sources that are derived from ruminant animals (cow, sheep, goat) have documentation that the component is in compliance with federal laws governing processing, use, and importation? That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.				

22.00	There are no preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).					X
23.00	There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA.					X
24.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.		X			
25.00	For **animal compounding**, does the compounding meet the same standards as compounding for human patients?					X
25.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.					
25.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.					
25.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.					
25.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.					
25.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					
26.00	If the pharmacy compounds **stock solutions** or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.					X
26.01	The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR there is documentation of stability or testing to support an extended BUD.					
26.02	Sterility testing is performed on stock solutions.					
26.03	Endotoxin testing is performed after sterilization on stock solutions to be used for parenteral preparations.					
26.04	Once punctured, the stock solution is discarded after 6 hours if kept in ISO Class 5 (or 1 hour if in less than ISO Class 5).					
26.05	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.					
Notes (refer to question number above)						

	Environment	Compliant	Non-Compliant	Unknown	N/A
27.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.				X
28.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.				X
28.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?				
29.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).	X			
30.00	The ante-room has a line of demarcation or other separation of the dirty to the clean side. *Note: the line of demarcation may NOT be the doorway between the ante room and the clean/buffer room.*	X			
30.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.	X			
30.02	Carts used in the clean room/buffer room are kept on the clean side of the line of demarcation.	X			
31.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	X			
32.00	Walls painted with epoxy based paint or other impermeable surface, and are seamless or have sealed seams where panels meet and corners with no cracks.	X			
33.00	The ceiling tiles are composed of a vinyl surface, with the tiles caulked and sealed and the seams where the walls meet the ceiling are caulked and sealed.	X			
34.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	X			
35.00	The clean room or ante-room does not have dust collecting overhangs, such as ceiling utility pipes, or ledges; and sprinkler heads are flush with the ceiling.	X			
36.00	The exposed surfaces of the light fixtures are smooth, mounted flush, and sealed.	X			
37.00	A sink with hot and cold running water is located on the clean side of the line of demarcation in the ante room that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and an eyewash station.	X			
38.00	Hand drying is with non-linting paper towels, or an electronic or HEPA filtered hand dryer.	X			

38.01		If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. (N/A if only using towels)				X
39.00	There is no sink or drain in the clean room/buffer room.		X			
40.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and ante room are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment.		X			
41.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the ante-room and clean room.		X			
42.00	If there is particle generating equipment in the clean room or ante-room (such as computers and printers), the equipment is located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use.		X			
43.00	If there are particle generating appliances in the clean room or ante-room (such as refrigerators, dishwashers, etc.), the equipment located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while the equipment was in use and appliances are also part of the viable surface sampling program.		X			
44.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean room/buffer area or ante-room.					
45.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.					X
45.01		RECOMMENDED: Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment				X
46.00	Completely enclosed ante room and clean room (with a door) are equipped with monitors or gauges to measure differential pressure		X			
46.01		Ante room is at least 0.02" w.c. positive pressure to general pharmacy areas	X			
46.02		Clean room/buffer room is at least 0.02" w.c. positive pressure to general pharmacy areas	X			
46.03		Hazardous compounding room and drug storage area is at least 0.01" w.c. negative pressure to ISO Class 7 ante room	X			
46.04		Pressures are read and recorded each shift (minimum of once daily) or are continuously recorded. *View logs*	X			
46.05		Plan in place to detect and react to pressure differentials outside of limits	X			

47.00	The clean room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.						X
47.01		The air flow is at least 40 feet per minute across the entire opening					
47.02		Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*					
47.03		Plan in place to detect and react to air flow measurements outside of limits					
47.04		This area is used only for low- and medium-risk compounding. (High-risk not allowed)					
48.00	**Temperature:** The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.		X				
48.01		Temperature in the **compounding area** is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements. Recommended temperature range for performing sterile compounding while garbed is between 64-72°F (18-22°C).	X				
48.02		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	X				
48.03		Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas).	X				
48.04		Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F).	X				
48.05		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	X				
48.06		Temperature in the **freezer** is maintained to provide controlled frozen temperature of -10° to -25°C (-13° to 14°F).	X				
48.07		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	X				
48.08		Action plan in place for temperature excursions including evaluating excursion effects on drug product integrity.	X				
49.00	**Humidity:** Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60% for performing sterile compounding.		X				
49.01		Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	X				
49.02		Excursion action plan in place including evaluating excursion effects on drug product integrity.	X				

49.03		Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).	X			
50.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.		X			
51.00	When the ISO 5 LAFW blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces		X			
52.00	The doors into the ante-room from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*		X			
53.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*		X			
53.01		RECOMMENDED: Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room (and NOT between the outside areas directly into the buffer room). Recommended				
54.00	RECOMMENDED: The immediate area around the doorway or pass-through into the ante room from the general areas is free of particle generating materials (such as currogated cardboard, etc.) and is located in an area that limits particles (not next to an outside door or window, etc.) to limit potential contamination from being brought in through the entry.					
55.00	**BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room:** BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.					X
55.01		Used only for low-risk compounded preparations with a 12-hour or less BUD assigned.				
55.02		All garbing requirements adhered to				
55.03		Located in an area that is maintained under sanitary conditions only be traveled by persons engaging in the compounding of sterile preparations				
55.04		Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?				
55.05		Has the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent) and an eyewash station				
56.00	**CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.					X
56.01		The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.				

56.02		The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.				
56.03		There is a sink in the compounding area, not directly adjacent to the CAI or CACI, that enables pharmacy personnel to wash hands and an eyewash station				
56.04		For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.				
Notes (refer to question number above)						

Cleaning and Disinfection		**Compliant**	**Non-Compliant**	**Unknown**	**N/A**
57.00	Are all personnel performing cleaning appropriately garbed?	X			
58.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	X			
59.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?	X			
60.00	Are reusable tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.	X			
61.00	Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?	X			
62.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present*	X			
63.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	X			
64.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	X			

65.00	Does the cleaning of the ISO 5 PEC include cleaning with sterile water **and** sanitizing with sterile 70% IPA using a nonlinting wipe?	X			
66.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	X			
67.00	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*	X			
68.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?				X
69.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?				X
70.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* Check inside bins and shelving for dust if you are garbed.	X			
71.00	Is enough time allocated for cleaning activities?	X			

Notes (refer to question number above)

Training			**Compliant**	**Non-Compliant**	**Unknown**	**N/A**
72.00		There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.*	X			
72.01		All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.	X			
72.02		All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.	X			
73.00		All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.*				X

74.00	There is documentation that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.	X			
75.00	There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. *Documentation needs to include training on operation, and troubleshooting*	X			
76.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*				X
77.00	There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs. *Indicate frequency in "Notes" below if testing more than annually.*	X			
78.00	There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs. *Compounding skills evaluation to include use of equipment. Indicate frequency in "Notes" below if testing more than annually.*	X			
79.00	There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency in "Notes" below if testing more than annually.*	X			
80.00	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Indicate frequency in "Notes" below if testing more than annually.*	X			
81.00	There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency in "Notes" below if testing more than annually.*	X			

82.00		The media-fill testing procedures include: • Media selection (including obtaining COAs or growth promotion certificates from suppliers) • Fill volume • Incubation time and temperature (30-35°C for a minimum of 7 days then 20-25°C for 7 days) • Inspection of filled units • Documentation • Interpretation of results (including identifying microbes down to genus level) • Action levels set with the corrective actions required	X			
83.00		**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU/plate upon revalidation.* *Indicate frequency in "Notes" below if testing more than every 6 months.*				X
84.00		**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.* *Indicate frequency in "Notes" below if testing more than every 6 months.*				X
85.00		**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.	X			
85.01		Gloved fingertip tests or media fill tests that failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.	X			
85.02		There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.	X			

Notes (refer to question number above)
79.00 - testing performed twice a year / 80.00 - testing performed twice a year. / 81.00 - testing performed twice a year.

	Compliant	Non-Compliant
Garbing		

	Garbing			Unknown	N/A
86.00	Personnel are prohibited from compounding, or entering the clean/buffer room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	X			
87.00	Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*	X			
88.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. when entering clean/buffer room.	X			
89.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	X			
90.00	Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe)	X			
91.00	Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask . Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a mirror available to check that all hair is covered.*	X			
92.00	Hand cleaning is performed in the ante-room and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	X			
93.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	X			
94.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	X			
95.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*	X			
96.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	X			
97.00	Pharmacists or other personnel do NOT enter the ante-room and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	X			
98.00	Pharmacists or other personnel do NOT enter the clean room without fully washing and garbing (wearing just a mask to check technician's work, for example)	X			
	Notes (refer to question number above)				

	Environmental Monitoring		Compliant	Non-Compliant	Unknown	N/A
99.00	The most recent PEC and room certification report is available.		X			
99.01		All ISO Class 7 and 8 SECs (cleanrooms and ante rooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification below.*	X			
99.02		All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification below.*	X			
99.03		Certification is performed at least every six months (view date of previous certification) and whenever a device or room is moved or major work is done to the space. *If non-compliant, record the date of the next previous certification below.*	X			
99.04		Certification is performed to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	X			
99.05		If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 standard.	X			
99.06		The PIC is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	X			
100.00	The certification report includes information about the equipment used for performing calibration test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due)		X			
100.01		The equipment used had not exceeded its calibration date at the time of certification	X			
101.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms		X			
101.01		ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH.*	X			

101.02		ISO class 7 ante-room is certified as having a minimum of 30 ACPH. *Ante room must be ISO class 7 if connected to a NIOSH hazardous compounding clean room.*	X			
101.03		ISO class 8 ante-room is certified as having the **recommended** minimum of 20 ACPH.	X			
101.04		ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*	X			
101.05		If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.				X
102.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the hoods and rooms). *The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.*		X			
102.01		Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	X			
102.02		Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs	X			
102.03		Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.	X			
103.00	Differential air pressure between rooms was measured.		X			
103.01		The differential pressure measured was at least 0.02" water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed.	X			
103.02		The differential pressure measured was at least 0.01" water column negative from the hazardous clean room to the ante room with the doors closed.	X			
104.00	Displacement airflow between rooms or areas was measured. *This is for a clean room without a door that closes to the ante room - may be an open space or may have plastic strips in doorways.*					X
104.01		Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*				
105.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.		X			
105.01		ISO Class 5 areas and hoods are certified as having less than 3,520 particles per cubic meter of air.	X			
105.02		ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air.	X			
105.03		ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air.	X			
106.00	HEPA filter tests were performed.		X			

106.01		All room HEPA filters were leak tested and if leaks found, they were fixed	X			
106.02		All hood HEPA filters were leak tested and if leaks found, they were fixed	X			

107.00	Rooms or hoods with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.		X			
108.00	Viable air and surface sampling tests have been conducted at least every 6 months. *If sampling is performed more often, document frequency below in "Notes".*		X			
108.01		Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*	X			
108.02		Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*	X			
108.03		Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and ante room and the samples are at least 400 liters in volume? *Note: recommendation in ISO 5 PEC is 1000 liters.*	X			
108.04		Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	X			
108.05		Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the number of CFUs found must be multiplied by the appropriate factor*	X			
108.06		CFUs detected by any means: (viable air or surface sampling, media fills, gloved fingertip testing, failed sterility tests, etc.) are analyzed to determine the organism down to the genus. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	X			
108.07		If the number of CFUs detected exceeds action levels, compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.	X			
108.08		If **any** mold, yeast, coagulase positive staphylococcus, or gram negative rods were detected (whether or not the number of CFUs exceeds action levels), compounding ceases, immediate remediation and investigation into the cause conducted, and compounding not resumed until subsequent tests are performed successfully.	X			

108.09		The testing report indicates growth promotion testing or documentation and sterility quality control testing of the media plates was performed. *Positive and negative control tests important to validate results of viable testing.*	X			
108.10		The testing results report includes media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer.	X			
109.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely validate sampling procedures. *Indicate the outside vendor used to validate procedures and frequency of validation below in "Notes".*		X			

Notes (refer to question number above)

108.00 - performed every other week / initial testing performed 01/27/2023 x 3 days of testing. Results indicated action plan required. Action plan performed. Restesting performed on 2/03/2023 - results indicated action plan required. Action plan performed. Retesting performed again on 2/27/2023 and again on 3/01/2023. Results of the 2/27/2023 and 3/01/2027 testing - passed for all areas.

Compounding Equipment		Compliant	Non-Compliant	Unknown	N/A
110.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	X			
111.00	All environmental monitoring equipment and guages (differential pressure guages or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.	X			
112.00	All temperature and humidity monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented	X			
113.00	Scales, balances, or other equipment used for measurement are regularly calibrated, and validated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used below in notes.*	X			
114.00	RECOMMENDED: PEC (hood) <u>prefilters</u> are checked and replaced regularly. *View replacement log or documentation of filter check and replacement by certification company .*				

115.00		Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.	X			
115.01		There is documentation of the ACD tubing being changed or discarded every 24 hours	X			
115.02		The ACD is used when performing media fill testing.				
Notes (refer to question number above)						

Compounding Procedures		**Compliant**	**Non-Compliant**	**Unknown**	**N/A**
116.00	Gloves and critical sites are sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a nonlinting wipe	X			
117.00	Objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	X			
118.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before bring brought into the buffer or clean area.	X			
119.00	Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	X			
120.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). If compounding not being performed, and personnel can adequately verbalize technique may mark compliant - note below that compliance was based on verbal explanation.*				
121.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	X			
122.00	All rubber stoppers of vials and bottles and the neck of ampules are sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product.	X			

123.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*		X			
124.00	The remaining contents of opened single-dose ampules are discarded immediately. *May not be stored for any time period.*		X			
125.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.		X			
126.00	The compounding record is complete. *View several completed compounds.* 1. Official or assigned name, strength and dosage of the preparation 2. Names, lot numbers and expiration dates of all components 3. Total quantity or number of units compounded 4. Person compounding the preparation 5. Person performing the quality control procedures 6. Person who approved the preparation 7. Date of compounding 8. Assigned internal identification number or prescription number 9. Assigned BUD and reference if extended beyond USP guidelines 10. Duplicate label 11. Sterilization method (if applicable) 12. Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable					
127.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is* ***recommended*** *to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*					
128.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.					X
128.01		RECOMMENDED: Labels on batch single-use containers are clearly marked as "Single Use Only"				
129.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or BUD, flow rate (if applicable), and appropriate packaging and labeling of hazardous materials.		X			
129.01		RECOMMENDED: Labels on patient-specific single-use containers are clearly marked as "Single Use Only"				
130.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**					

131.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen	X			
132.00	Extended BUDs are assigned and are supported with stability documentation. *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*				X
133.00	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below.*				X
134.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.				X
135.00	**Filter sterilization** in an ISO 5 environment and documentation includes: 1. The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling does not indicate "research only", for example). 2. That filtering is completed rapidly without filter replacement 3. Confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration. *View documentation on compounding records of items sterilized by filtration to confirm.*				X
136.00	**Steam sterilization** documentation includes: 1. The autoclave has been validated for the exposure time and mass of the items to be sterilized 2. Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices 3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization 4. Heated filtered air is evenly distributed throughout the chamber with a blower 5. That the CSP will not be adversely affected by the steam and heat 6. The description of steam sterilization includes conditions and duration for specific CSPs				X
137.00	**Dry heat sterilization** documentation includes: 1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture 2. Sufficient space is left between materials to allow for air circulation 3. The description of dry heat sterilization includes conditions and duration for specific CSPs 4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators 5. The oven is equipped with a system for controlling and recording temperature and exposure period				X

138.00	**Depyrogenation by dry heat** documentation includes: 1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes 2. The description of the cycle and duration for specific load items 3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs) 4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins				X
139.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method in Notes below.*				X

Notes (refer to question number above)
Firm does not utilize extended BUD's.

Finished Preparation Release Checks and Tests			**Compliant**	**Non-Compliant**	**Unknown**	**N/A**
140.00		Are products checked for particulates or other foreign matter against both a light and a dark colored background?	X			
141.00		Are there checks for container and closure integrity?	X			
142.00		Is compounding accuracy documented by verification of steps?	X			
143.00		Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	X			
144.00		Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	X			
145.00		**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe in "Notes" below.*				X
145.01		Sterility testing includes both bacterial and fungal testing.				
145.02		Sterility testing is performed for all CSPs that have extended BUDS.				
145.03		Sterility testing is performed for CSPs prepared in batches of more than 25 identical containers				
145.04		Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized				

145.05		The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Less than 100, test 10% or four units, whichever is greater 2. 100 up to 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Less than 200 containers, test 5% or 2 containers, whichever is greater 2. 200 or more containers, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.				
145.06		For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken.				
145.07		If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk.				
146.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe in "Notes" below.*					X
146.01		Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials)				
146.02		High-risk CSPs prepared in multiple dose vials for administration to multiple patients,				
146.03		High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized				
146.04		For products failing testing, product is quarantined, and an investigation is performed and action taken.				
147.00	RECOMMENDED: **Potency testing is performed.** *Describe for which products or circumstances potency testing is performed in "Notes: below*					X
148.00	View testing records. Products that have failed sterility, endotoxin, purity or potency testing have been quarantined and destroyed, or recalled if dispensed or distributed, and appropriate investigation performed to determine cause and correction or training performed to prevent future occurrence.					
Notes (refer to question number above)						

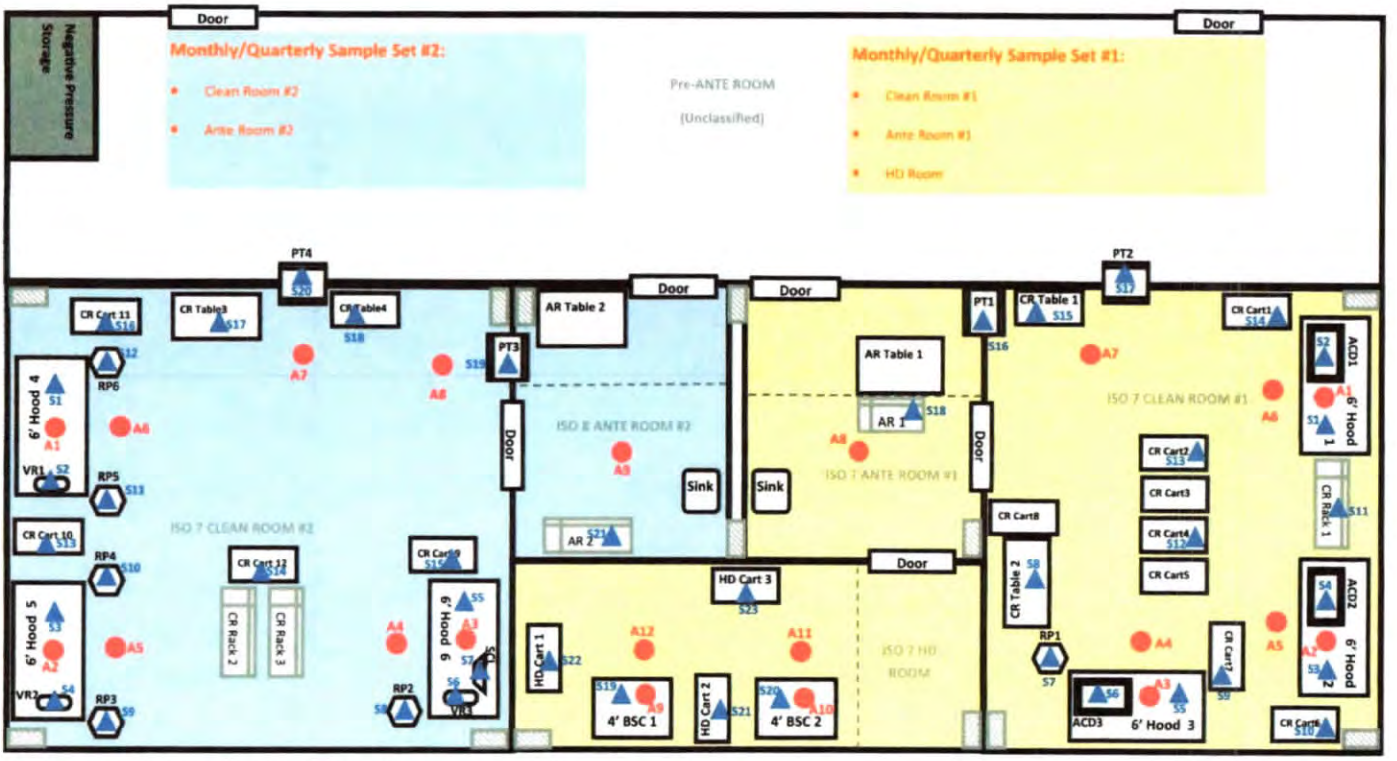
Patient Counseling and Communication		Compliant	Non-Compliant	Unknown	N/A
149.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?				X
150.00	Compounding pharmacies: Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products? How?	X			
151.00	Compounding pharmacies: Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	X			
152.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.	X			
Notes (refer to question number above)					
150.00 - firm provides written monograph information for each active ingredient of the dispensed compound. 151.00 - pharmacist outreach to patient to provide additional information relative to the compounded product					

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

Optum Infusion Services—CHANDLER JUNIPER—Viable Sampling SPC Map

- SURFACE samples must be taking place in areas of high traffic, high activity and where products are exposed
- ISO 5 Hoods and Work Benches must be sampled in the DIRECT COMPOUNDING area
- All SURFACE and AIR samples must be taken in order as indicated on this map

▲ MONTHLY surface sampling ● QUARTERLY air sampling



PT = Pass Through; RP = Repeater Pump; VR =Vial Roller; ACD = PN Compounder; SCL= Scale

Occupancy for Dynamic Condition: 6 personnel in each Clean Room, 4 personnel in each ante room, and 3 personnel in HD Room

Last updated 03/09/2023

VIPPs Inspection
Optum Infusion Services #398 (Y005288)
Compliance Officer Time
6/18/2023 11:55

Date - 5/25/2023	Begin	End	Inspect Time	Travel Time	Document Summary	Total Time (hrs:min)
Steve Haiber	9:15	17:45	8:30	1:00	1:00	10:30
Chirag Patel	9:15	17:45	8:30	2:00		10:30
Total CO Time to inspect including travel						**21:00**

	$ Rate / hr	Total Time (hours)	Total Charges
Total Charges to Invoice Permit Holder	$ 56.25	**21.00**	$ 1,181.25

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

Optum Infusion Services 308, LLC

ACC file number: L12415047

was incorporated under the laws of the State of Arizona on 11/09/2005, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **12/18/2024**

SEAL OF THE ARIZONA CORPORATION COMMISSION * 1912 * DITAT DEUS

Douglas R. Clark, Executive Director

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Optum Infusion Services 308, LLC
Address :	485 N. Juniper Drive Suite 2 Chandler AZ 85226
Registration No :	Y005288
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	06/25/2010
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 12/27/2024

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/08/2024
Receipt Number: 2024179573
Receipt Amount $: 480.00

Pharmacy - Limited Service

Compounding – Sterile,Retail

PERMIT NO	**EXPIRES**
Y005288	**10/31/2026**

Issued to :

Optum Infusion Services 308, LLC
Optum Infusion Services 308, LLC
485 N. JUNIPER DRIVE SUITE 2
CHANDLER , AZ 85226

Optum Infusion Services 308, LLC
485 N. JUNIPER DRIVE SUITE 2
CHANDLER , AZ 85226

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Optum Infusion Services 308, LLC
LICENSE NUMBER : Y005288
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

• Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.

• You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

• Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law

• In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.

• Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Optum

Owner and Officer List

Applicant	Title	% of Ownership	Business Address
Optum Infusion Services 308, LLC	Owner	100%	485 N. Juniper Drive, Ste 2 Chandler AZ 85226
Tax ID: 20-3741084			
Parent Company	**Title**	**% of Ownership**	**Business Address**
SCP Specialty Infusion, LLC	Parent Company	100%	15529 College Blvd. Lenexa, KS 66219
Tax ID: 27-2635371			
Officers of Applicant	**Title**	**% of Ownership**	**Business Address**
Erin Satterwhite	President & CEO	0%	1 Optum Circle, Ste 100 Eden Prairie, MN 55344
Kevin Burr	Secretary	0%	1 Optum Circle, Ste 100 Eden Prairie, MN 55344
Marilyn Hirsch	Treasurer	0%	1 Optum Circle, Ste 100 Eden Prairie, MN 55344

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS2161343	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-02-2022

OPTUM INFUSION SERVICES 308, LLC
485 N JUNIPER DR
STE 2
CHANDLER, AZ 85226

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS2161343	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-02-2022

OPTUM INFUSION SERVICES 308, LLC
485 N JUNIPER DR
STE 2
CHANDLER, AZ 85226

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Polomar Specialty Pharmacy, LLC

Physical Address: 32866 US Highway 19N

City: Palm Harbor State: FL Zip: 34684

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-202-2217 Toll Free # (NAC 639.708, NRS 639.23286): 800-827-3064

Fax: 727-361-6197 Contact Email: kmattera@gldlp.com

Website: www.polomarspecialtypharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Nahla A. Ahmed

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24375

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nahla A. Ahmed	NV Pharmacist Registration #: 24375
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Kimberly Mattera

Business Name: _____

Business Address: 861 Johnson Ave

City: Myrtle Beach State: SC Zip: 29577

Telephone: 917-414-2469 Email: kmattera@gldlp.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Sole Member (title) for Polomar Specialty Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kimberly Mattera

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/6/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kimberly Mattera

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kimberly Mattera — 11/6/2024

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 11/12/24	Amount: $500 CK 3041

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Polomar Specialty Pharmacy, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 32866 US Highway 19N

City: Palm Harbor State: FL Zip: 34684

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-202-2217 Toll Free # (NAC 639.708, NRS 639.23286): 800-827-3064

Fax: 727-361-6197 Contact Email: kmattera@gldlp.com

Website: www.polomarspecialtypharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Nahla Ahmed

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24375

Name of Designated Person(s) as defined by revised USP-797 guidelines: Nahla Ahmed

Email of Designated Person(s): admin@polomarspecialtypharmacy.com

Telephone of Designated Person(s): 813-707-4186

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   [ ] Category 1 [■] Category 2 [ ] Category 3

If you marked "Category 3", you must also complete section 4.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? [■] Yes [ ] No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? [■] Aseptic [ ] Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? [■] Yes [ ] No

5. When was the most recent certification for the ISO classified areas? 08/02/2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 Months

7. Were there any follow-up items required from the most recent certification report? [ ] Yes [■] No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? [■] Yes [ ] No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? MONTHLY

10. Will you be performing sterile hazardous drug compounding? [ ] Yes [■] No

If you marked "Yes", you must also complete section 3.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

1- Semaglutide/Cyanocobalamine 5mg/1mg/ml vials
   Semaglutide/Cyanocobalamine 2.5mg/1mg/ml vials
   Semaglutide/Cyanocobalamine 1mg/1mg/ml vials
2- Tirzepatide/Cyanocobalamine 20mg/1mg/ml vials
   Tirzepatide/Cyanocobalmine 10mg/1mg/ml vials

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Laboratory

Address: 11680 28th Street N

City: St. Petersburg State: FL Zip: 33716

Telephone: (727) 209-5778

13. What is your procedure for visual inspection of compounded sterile products?
1. Determine if the finished preparation appearance is as expected (correct final fill volume).
2. Remove any temporary labels on container prior to performing inspection.
3. Ensure preparation labels not on the preparation containers are isolated and segregated from other preparations.
4. Mix the contents of the container by inversion while ensuring no air bubbles are introduced during the process.
5. Examine preparations against a matt black background and against a non-glare white background using an incandescent light.
6. Use higher illumination intensity sufficient to detect particles for preparations where solutions are colored, opaque or in containers other than clear glass.
7. Inspect for: viable and non-viable particulates, leakage, cloudiness, improper seal, crystals, discoloration, precipitation

14. How often do you perform glove fingertip and medial fill testing?
Fingertip testing: Initially and every 6 months (CAT 2)
Medial fill testing: Initially and every 6 months (CAT 2)

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
1.Hand hygiene.
2.Garbing (i.e., gloving, donning and doffing for non-hazardous drug handling and compounding).
3.Handling, receiving, unpacking and storing procedures.
4.Proper use of primary engineering controls (PECs)
5.Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 environment.
6.Sanitization Procedures (i.e., cleaning and disinfecting).
7.Aseptic techniques, which includes its assessment by:
a.Gloved fingertip and thumb sampling.
b.Media-fill testing.
8. Enviromental assessments (Air sampling and surface sampling)

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
PEC and Equipements inside:
1. Cleaning agent: Equipment and all interior surfaces of the PEC daily on days when compounding occurs and weekly if no compounding occurs and when surface contamination is known or suspected. (DECON-QUAT)
2. Disinfectant agent: Equipment and all interior surfaces of the PEC daily and before and after compounding and when surface contamination is known or suspected. (sIPA 70%)
(Disinfectant is used monthly also to remove any residues of Sporicidal agent.).
3. Sporicidal agent: Monthly for compounding Category 2 CSPs (DECON-SPORE)
and before introducing any equipment to the cleanroom

Sequence of cleaning PEC: Ceiling->walls, back of PEC->items on the DCA->DCA
Top to bottom, Left to right
(our SOPs has detailed description of the whole procedure of cleaning PEC and SEC)

Floors of SEC and Anteroom: daily (Cleaning agent), Monthly (Sporicidal)
Walls and Ceiling of SEC and Anteroom: Monthly (Sporicidal)

17. Who performs the sterile compounding process at your facility?

Designated Person: RPH Nahla Ahmed, Pharmacy technician: RPT Marry Hanna

18. Who is responsible and accountable for the sterile compounding process at your facility?
Designated Person: RPH Nahla Ahmed

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Products will be shipped along with an ice pack to maintain storage requirements of the vials which should be within 2-8 degrees Celsius to ensure safety and efficacy.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐Yes ☐No

4. What is the frequency for completing volumetric active air sampling?
N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nahla Ahmed

Name of Person who Completed the Form

Designated Person & Pharmacist in Charge

Title

Nahla Ahmed

Signature (copies or stamps not accepted)

10-31-2024

Date

Board Use Only	Date Received: 11/12/24 Date Approved: _____ Approved By: _____

State of Florida
Department of State

I certify from the records of this office that POLOMAR SPECIALTY PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on April 26, 2023.

The document number of this limited liability company is L23000206909.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Third day of October, 2024 .

Secretary of State

Tracking Number: 8976919834CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

File # 29858
Insp # 199425

NAME	PERMIT NUMBER	DATE OF INSPECTION
Polomar Specialty Pharmacy LLC		08/26/2024
DOING BUSINESS AS POLOMAR SPECIALTY PHARMACY LLC		
STREET ADDRESS 32866 US Highway 19N	**TELEPHONE #** 727-202-2217	**EXT**
CITY PALM HARBOR	**COUNTY** PINELLAS	**STATE/ZIP** FL/34684

Additional Information

Business Operation Hours

M-T-W-TH-F N	Monday Y
Monday Hours 9am-5pm	Tuesday Y
Tuesday Hours 9am-5pm	Wednesday Y
Wednesday Hours 9am-5pm	Thursday Y
Thursday Hours 9am-5pm	Friday Y
Friday Hours 9am-5pm	Saturday Y
Saturday Hours 9am-5pm	Sunday N

Registered Pharmacist / Intern / Tech

License # PS 63871	Licensee Name H Gerges
License Type Registered Pharmacists	
License # PS 67022	Licensee Name N Ahmed
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FP3780372	

License Relations

RX DPT MGR/COR/POR

GERGES, HANY NADER SAID	License # 63871

Special Sterile Compounding

POLOMAR SPECIALTY PHARMACY LLC	License # 34609

INV797 - USP Sterile Compounding

A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3]	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A

BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3]	N/A
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based. Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13]	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13]	Yes
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13]	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13]	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1]	Yes
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3]	Yes
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3]	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	Yes
GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	Yes
EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Documented in compounding record.*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1]	Yes
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *Walls to RHS of LAFW have been sealed.*	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall returns added in ante room, BSC running continuously. Smoke studies with Certification 7/19/24.*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Floor in doorway has been made smooth.*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5]	Yes
CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2]	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *Documented daily.*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0]	Yes
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *Last certification 7/19/24-TSS*	Yes

ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4]	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0]	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0]	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0]	Yes
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2]	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *BSC in ante room.*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *07/19/24 -Reviewed by HG.*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3] *Facility will follow Category 2 testing.*	Yes
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	N/A
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.6 & 16.1]	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	N/A
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	N/A
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	N/A
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *Plan to compound batch of 100.*	Yes

STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	N/A
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	N/A
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	N/A

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4 3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2] *TRC*	Yes
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	Yes

INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Previously reviewed at previous inspection, only 1 assessment.*	No
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2] *Reviewd at previous inspection, incubator temperatures will be added.*	No
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3]	Yes
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3] *Will add details, reviewed during initial inspection.*	No
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	N/A
CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	N/A
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1]	N/A
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	Yes
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6]	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area (e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2]	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1]	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3]	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	Yes
INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1]	N/A
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3]	N/A

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7]	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1]	Yes
REUSABLE GARB: Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3]	Yes
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7]	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1]	Yes
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7].	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes
MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7]	
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *BSC in ISO 8 ante room, ante room may be changed to smaller area between buffer rooms with addition of CVE.*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	N/A
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3]	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1]	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1]	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2]	Yes
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	Yes
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identity, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3]	Yes

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview	No
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10]	Yes
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10]	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10]	Yes
STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10]	N/A
CSP Sterilization by Filtration	No
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2]	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2]	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	N/A
CSP Sterilization by Steam	No
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3]	N/A
CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3]	N/A
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3]	N/A
CSP Sterilization by Dry Heat	No
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4]	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4]	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4]	N/A

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10]	Yes
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1]	N/A
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1]	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1] *MFR in Pioneer.*	Yes
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1]	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)]	Yes

COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2]	Yes
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)]	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4]	N/A

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *Compounding Document and Master Formulation Record.*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1]	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1]	N/A
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1]	N/A
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1]	N/A

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1]	Yes
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1]	N/A
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2]	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18]	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3]	N/A
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1]	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18]	N/A
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1]	N/A
ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18]	N/A
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *Initial inspection.*	N/A
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	Yes
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20]	Yes
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20]	N/A

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	

HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2]	
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5]	
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1]	
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2]	
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3]	
C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3]	
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2]	
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2]	
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressure in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1]	
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	
SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6]	
INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	

ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2]	
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterile starting components are compounded inside a sterile suite. [USP 800 Section 5.3.2]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3]	
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15]	
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15]	
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4]	
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2]	
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15]	
LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2]	
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Sections 11.1 & 13]	
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas, restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	
SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16]	
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	

The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.],	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Remarks:

Facility will complete required testing for Category 2 BUD.
Facility has added low wall returns in ante room.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

STAIKOS, GILLIAN

Date:8/26/2024

Representative:

N Ahmed

Nadia Ahmed

Date:8/26/2024

October 26, 2024

Hayes Attia
Polomar Specialty Pharmacy
32866 Us Highway 19 N
Palm Harbor, FL 34684

RE: License Certification for Polomar Specialty Pharmacy LLC

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH35196
ORIGINAL CERTIFICATION:	07/13/2024
EXPIRATION DATE:	02/28/2025
CURRENT STATUS OF LICENSE:	CLEAR
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

Your license number is PH 35196.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JULY 13, 2024	PH 35196	143380

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2025**

POLOMAR SPECIALTY PHARMACY LLC
32866 US HIGHWAY 19N
PALM HARBOR, FL - 34684

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO	CONTROL NO
JULY 13, 2024	PH 35196	143380

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

POLOMAR SPECIALTY PHARMACY LLC Expiration Date: FEBRUARY 28, 2025

REGISTRANT SIGNATURE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Polomar Specialty Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): PH 35196

Physical Address: 32866 US Highway 19N

City: Palm Harbor State: FL Zip: 34684

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 727-202-2217 Website: www.polomarspecialtypharmacy.com

Licensing Company Email: kmattera@gldlp.com

Section 2: Personal Information

First: Nahla Middle: Abdelmoaty Last: Ahmed

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Addr: [redacted]

City: Oldsmar State: FL Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Assuit university, Faculty of pharmacy		1999-2004	
Address	**City**	**State**	**Zip**
Asyut 1	Assuit Governorate	Egypt	
Diploma/Degree obtained, if any			
Bachelor's degree in pharmaceutical sciences			

School Name		From - To (MM/YY – MM/YY)	
Aswan Language School (High School)			
Address	**City**	**State**	**Zip**
	Aswan Governorate	Egypt	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	
2022-2024	[redacted]	Oldsmar	FL	[redacted]
2020-2021		Oldsmar	FL	
2018-2019		Palm Harbor	FL	
2014-2018		Aswan	Egypt	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Polomar Specialty Pharmacy			(05/2024 - Current date)
Business Address	**City**	**State**	**Zip**
32866 US Hw, 19N	Palm Harbor	FL	34684
Phone	**Title**	**Number of Employed Hours**	
727-202-2217	Staff Pharmacist	800 Hours	
Description of Duties			
Overseeing the day-to-day operations of pharmacy, Ordering Medications, Maintaining medication inventory, Training pharmacy technicians, Prescription Verification and Patient Counseling.			

Business Name			From - To (MM/YY – MM/YY)
Polomar Specialty Pharmacy			(6/2023- 5/2024)
Business Address	**City**	**State**	**Zip**
32866 US Hw, 19N	Palm Harbor	FL	34684
Phone	**Title**	**Number of Employed Hours**	
727-202-2217	Pharmacy Intern	1920 Hours	
Description of Duties			
Ordering Medications, Compounding, Maintain Inventory, Prepare and Dispense Medication, Use Technology to Print Labels, Enter Patient Data, Process Prescriptions, Shipping			

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			(01/2021 - 05/2024)
Business Address	**City**	**State**	**Zip**
700 East Lake Rd	Palm Harbor	FL	34685
Phone	**Title**	**Number of Employed Hours**	
727-785-6838	Certified Pharmacy technician	580 Hours	
Description of Duties			
Ordering Medications, Compounding, Maintain Inventory, Prepare and Dispense Medication, Use Technology to Print Labels, Enter Patient Data, Process Prescription, Shipping			

Business Name			From - To (MM/YY – MM/YY)
American Affordable Drugs Pharmacy			(03/2021 - 5/2023)
Business Address	**City**	**State**	**Zip**
32866 US Hw, 19N	Palm Harbor	FL	34684
Phone	**Title**	**Number of Employed Hours**	
813-999-2700	Pharmacy Intern	2080 Hours	
Description of Duties			
Ordering Medications, Compounding, Maintain Inventory, Prepare and Dispense Medication, Use Technology to Print Labels, Enter Patient Data, Process Prescription, Shipping			

Business Name			From - To (MM/YY – MM/YY)
Absolute Compounding Pharmacy			(01/2020 - 10/2020)
Business Address	**City**	**State**	**Zip**
16011 N Nebraska Ave Unit 103	Lutz	FL	33549
Phone	**Title**	**Number of Employed Hours**	
813-999-2700	Pharmacy Intern	1600 Hours	
Description of Duties			
Compounding, Filling, Shipping, Inventory management.			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Nahla Ahmed, **certify that as the designated representative for**

Polomar Specialty Pharmacy llc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NA I am at least 21 years of age;
3. NA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nahla Ahmed

Print Name (First, Last)

Nahla Ahmed

Original Signature (electronic, copies or stamps not accepted)

10/31/2024

Date 10/31/2024

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nahla Ahmed
Print Name (First, Last)

Nahla Ahmed — 10/31/2024
Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Nahla Ahmed, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nahla Ahmed — 10/31/2024
Original Signature — **Date**

Subscribed and Sworn to before me this 31 day of October 2024

Notary Public Signature

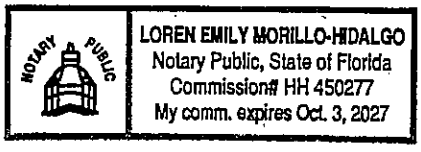
Please see attached document for updated Notary Block and stamp from Emily Morillo-Hidalgo

(Seal)

Document Name: Nevada State Board of Pharmacy

State of Florida Jurat Notary Certificate

STATE OF FLORIDA
COUNTY OF PINELLAS
Sworn to (or affirmed) and subscribed by personally appearing before me by physical presence this 31 day of October, 2024, by, Nahla Ahmed (name of person making statement).



Loren Emily Morillo-Hidalgo
(Signature of notary public)

Loren Emily Morillo-Hidalgo
(Name of notary public)

My commission expires: October,3.2027

Official Seal

Personally known OR
Produced identification X Type of identification produced: Florida Driver License

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Polomar Specialty Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 32866 US Highway 19N

City: Palm Harbor State: FL Zip: 34684

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 727-202-2217 Website: www.polomarspecialtypharmacy.com

Licensing Company Email: kmattera@gldlp.com

Section 2: Personal Information

First: Kimberly Middle: Ann Last: Mattera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Myrtle Beach State: SC Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Totenville High School		09/85-06/89	
Address	**City**	**State**	**Zip**
100 Luten Avenue	Staten Island	NY	10312
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23 - Present	[redacted]	Myrtle Beach	SC	[redacted]
01/10 - 05/23	[redacted]	Staten Island	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Vesey Enterprises, Inc.			06/2013 - Present	
Business Address	**City**		**State**	**Zip**
168 Central Avenue	Farmingdale		NY	11735
Phone	**Title**			
212-245-3413	President & Owner			
Description of Duties				
President and Owner of Holding Company for Various Business Interests				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kimberly Mattera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/6/2024

Date

Please have this section completed in the presence of a Notary Public.

State of SOUTH CAROLINA, ss. County of HORRY

I, KIMBERLY MATTERA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/6/2024

Date

Subscribed and Sworn to before me this 6 day of NOVEMBER 2024

Notary Public Signature

THOMAS FISHER
NOTARY PUBLIC
MY COMMISSION EXPIRES
OCTOBER 25, 2026
SOUTH CAROLINA

(Seal)

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FS4162551
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH new application		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Super Saver Pharmacy #4 dba Rush Pharmacy

Physical Address: 1977 Alafaya Trail Suite 1121

City: Oviedo State: FL Zip: 32765

Mailing Address (if different from physical address): (same address)

City: _____ State: _____ Zip: _____

Telephone: 4075420880 Toll Free # (NAC 639.708, NRS 639.23286): 877-752-0608

Fax: 8669138207 Contact Email: licensing@rushpharmacy.com

Website: www.rushpharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Christian Cox

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24245

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christian Cox	NV Pharmacist Registration #: 24245
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required. *Brent Messer (2003) expunged - See Personal History

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Brent Messer

Business Name: Super Saver Pharmacy #4, LLC dba Rush Pharmacy

Business Address: 1977 Alafaya Trail Suite 1121

City: Oviedo State: FL Zip: 32765

Telephone: 407-542-0880 Email: licensing@rushpharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Rush Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Brent Messer

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/24/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Messer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/24/24

Date

Board Use Only	Date Received: 10/7/24	Amount: $500-cc

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Super Saver Pharmacy #4, LLC dba Rush Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): new application

Physical Address: 1977 Alafaya Trail Suite 1121

City: Oviedo State: FL Zip: 32765

Mailing Address (if different from physical address): (same)

City: State: Zip:

Telephone: 407-542-0880 Toll Free # (NAC 639.708, NRS 639.23286): 407-542-0880

Fax: 866-913-8207 Contact Email: licensing@rushpharmacy.com

Website: www.rushpharmacy.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Christian Cox

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24245

Name of Person with direct knowledge of compounding procedures: Christian Cox

Email of Person with direct knowledge of compounding procedures: licensing@rushpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 407-542-0880

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Semaglutide inj
Tirzepatide inj
Trimix inj

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Antimicrobial Effectiveness Test
Method of Suitability Test
Container Closure Integrity Test

6. What laboratory performs this additional testing?
Name: Eagle Analytical
Address: 11111 S. Wilcrest Dr., Suite 1000
City: Houston State: Tx Zip: 77099
Telephone: 800 745 8916

7. What is your procedure for visual inspection of compounded sterile products?
We use a light-Dark box to check for contaminants

8. How often do you perform glove fingertip and medial fill testing?
Every 6 mo

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Must retest and can't compound until they pass.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial: 3rd Party Sterile Training program + Media fill and glove fingertip test
Annual: Online didactic CEs through Lyceum CE built in our software system (LifeFile)

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
PEC: Cleaned daily when ~~used~~
- Sterile TBI followed by Sterile 70% IPA inside Hood
- Sterile Peridox followed by Sterile 70% IPA inside hood (monthly)

SEC: Cleaned daily when used (Floors, counters, carts, pass through, work surfaces)
- PreEmpt plus followed by Sterile 70% IPA if residue present

Monthly: includes daily cleans plus ceiling, door, door handle

12. Who performs the sterile compounding process at your facility?
Lead Sterile Technician: Heather C., CPhT, PTCB

13. Who is responsible and accountable for the sterile compounding process at your facility?
Christian Cox, PharmD (PIC)

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
All products are shipped in boxes.
Temperature sensitive products are shipped in insulated boxes w/ a 24oz ice pack wrapped in silver insulated bubble wrap.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) N/A

1. What type of primary engineering controls will you be using in your facility?
~~LAFW~~

2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Semaglutide inj
Tirzepatide inj
Trimix

2. What sterilization methods are utilized at your facility?

Autoclave: Stoppers and Seals, 121°C, 15 psi, x 20min
Oven: Glassware, 250°C x 30min (Beakers)
We use prestirilized vials

3. Does your facility utilize biological indicators? ☒ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are placed in both the autoclave and oven with each cycle. After cycle completion, the indicator is activated and incubated per manufacturer instructions. Items sterilized are not used until the incubation for the incubators are complete and shows no bacteria growth.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christian Cox
Name of Person who Completed the Form

Pharmacist-in-Charge
Title

Christian Cox
Signature (copies or stamps not accepted)

5/9/24
Date

Board Use Only	Date Received: 10/7/24 Date Approved: _____ Approved By: _____

Detail by Entity Name

Florida Limited Liability Company
SUPER SAVER PHARMACY #4, LLC

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Principal Address

1977 ALAFAYA TRAIL,
SUITE 1121
OVIEDO, FL 32765

Changed: 12/28/2018

Mailing Address

1977 ALAFAYA TRAIL,
SUITE 1121
OVIEDO, FL 32765

Changed: 12/28/2018

Registered Agent Name & Address

DAWOUD, ROSEMARY
1977 ALAFAYA TRAIL,
SUITE 1121
OVIEDO, FL 32765

Name Changed: 03/05/2017

Address Changed: 03/19/2021

Authorized Person(s) Detail

Name & Address

Title MGR

DAWOUD, ROSEMARY
[redacted]
SANFORD, FL [redacted]

Annual Reports

Report Year	Filed Date
2021	03/19/2021
2022	05/03/2022
2023	03/28/2023

Document Images

03/28/2023 -- ANNUAL REPORT	View image in PDF format
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03/05/2017 -- ANNUAL REPORT	View image in PDF format
10/13/2016 -- LC Amendment	View image in PDF format
10/04/2016 -- CORLCDSMEM	View image in PDF format
10/04/2016 -- CORLCDSMEM	View image in PDF format
10/04/2016 -- Reg. Agent Resignation	View image in PDF format
10/04/2016 -- LC INTEREST EXCHANGE	View image in PDF format
04/29/2016 -- ANNUAL REPORT	View image in PDF format
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03/12/2013 -- ANNUAL REPORT	View image in PDF format
04/27/2012 -- ANNUAL REPORT	View image in PDF format
04/26/2011 -- ANNUAL REPORT	View image in PDF format
10/08/2010 -- Florida Limited Liability	View image in PDF format

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

www.FloridaHealth.gov

File # 29925
Insp # 200346

NAME	PERMIT NUMBER	DATE OF INSPECTION
SUPER SAVER PHARMACY #4		09/12/2024
DOING BUSINESS AS		
RUSH PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
1977 ALAFAYA TRAIL SUITE 1121	315-217-1237	
CITY	**COUNTY**	**STATE/ZIP**
OVIEDO	SEMINOLE	FL/32765

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:00 am to 4:30 pm
Monday Y	Monday Hours
Tuesday Y	Tuesday Hours
Wednesday Y	Wednesday Hours
Thursday Y	Thursday Hours
Friday Y	Friday Hours
Saturday Y	Saturday Hours closed
Sunday Y	Sunday Hours closed

Registered Pharmacist / Intern / Tech

License # PS59749	Licensee Name Christian Cox - PDM
License Type Registered Pharmacists	
License # PS47650	Licensee Name Patricia Cook
License Type Registered Pharmacists	
License # RPT 52778	Licensee Name Heather Clevenger
License Type Pharmacy Tech	
License # RPH56422	Licensee Name Arielle Rodriguez
License Type Pharmacy Tech	
License # RPT 103717	Licensee Name Caitlin Newkirk
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FS4162551	

License Relations

Pharmacy Affiliate

MESSER, BRENT	License #

RX DPT MGR/COR/POR

COX, CHRISTIAN RENFORD	License # 59749

Special Sterile Compounding

SUPER SAVER PHARMACY #4, LLC	License # 25118

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Persons : Christian Cox, Patricia Cook.*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *per SOP 2.043*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13] *Sample label reviewed does not state the dosage form on Semaglutide/Pyridoxine 0.25mg/5mg/0.5ml inj vial label*	No
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)] *Retail establishment*	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Protect from Excess light warning statement is not specified in MFR or labels.* *Please update MFR and add auxiliary "Protect from Excess Light" labels.*	No
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *Labels updated to reflect "Compounded Product" per SOP*	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13]	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1]	Yes
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3] *CC had to repeat donning of gown the second time. Please reeducate on proper donning of coverall.*	Yes
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Alcare Plus hand sanitizer is not hands free- noted posted on wall of ante room.*	Yes

STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	Yes
GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3] *Garb stored in lidded tubs on bottom of cart to left of sink*	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	Yes
EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *per Compounding 360 and noted on sample batch record.*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *Autoclave Tuttnauer SN 23070683 calibrated 9-13-23 (almost due-was being recalibrated on day of inspection-report is pending)* *Baxter Repeater Pump SN PL0024668 inspected 5/31/24 by IMS* *Crosstex SPS Dry Block Incubator Lot# 78853 QA completed 3-12-24* *Ohaus Scale SN C404529341 and SNC232605120 calibrated 3-3-24* *Large Incubator 1 SN F-04349 calibrated 12-21-23* *Small Incubator 2 SN P-06514 calibrated 1-30-24* *Binder Dry Heat Oven calibrated 2-21-24* *Ohaus PH meter SN 2353799489 CofC 5/21/24* *Millex Integrity Tester Jan 2024* *Sonicu monitor for temp calibrated 5/24/24*	Yes
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4] *API's are stored in freezer under Sonicu temp monitoring system.*	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *ISO 8 Ante room, with a door backed into that opens into the ISO 7 non-HD buffer room.*	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall vent returns*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1] *Rust noted on left upper leg of steel table was fixed during inspection.*	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Ceilings tiles are caulked*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5] *Underside of PEC appeared clean and was verified to be PVC Celtec Foam per letter from manufacturer. See attached.*	Yes

CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5] *Steel carts*	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *Sonicu temp and humidity monitoring system transfers to Compounding 360. Monitor noted during walkthrough of ante room.*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *Documentation maintained in Compounding 360*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0] *Last completed May 20, 2024 and June 25, 2024 under dynamic conditions.*	Yes
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *June 25, 2024 updated to report "1 person weighing in hood while unit tested"*	Yes
ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4] *June 25, 2024 Buffer room (ISO 7) 41.7 ACPH including 11 ACPH from the PEC, Ante room 39.8 ACPH.*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Documented as 1 person present*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0]	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0]	Yes
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2]	N/A
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *Certifier PASC certified CVE 3/7/24 and 9/6/24 (past Friday)*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0]	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in e cleanroom suite with en ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3]	Yes

CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *Pharmacy states they will not be terminally sterilizing CSP's.*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	N/A
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Available AET USP<51> testing from Eagle Analytical for Semaglutide 2.5mg/0.5ml Injection Lot LG339000163 (under conditions of refrigeration-Scan RDI Method Suitability Test), Semaglutide 2.5mg/Pyridoxine 5mg/0.5ml Lot LG339000181(refrigerated), and Tirzepatide 15mg/Pyridoxine 5mg/0.5ml (refrigerated) Lot LG339000179.*	Yes
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	Yes
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2] *Lots specifically compounded for testing-sent to Eagle for AET testing, Method Suitability testing and Container closure testing-per Life File dispense records-no dispensing from these lots to patients.*	N/A
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2] *Available from Eagle Analytical for Semaglutide 2.5mg/0.5ml Injection Lot LG339000163 (under conditions of refrigeration-Scan RDI Method Suitability Test), Semaglutide 2.5mg/Pyridoxine 5mg/0.5ml Lot LG339000181(refrigerated), and Tirzepatide 15mg/Pyridoxine 5mg/0.5ml (refrigerated) Lot LG339000179.*	Yes
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *Batch record reviewed: Semaglutide/Pyridoxine 2.5mg/0.5ml Inj 2ml-qantity made for testing was 216 vials.*	Yes
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *Quantity to be sent for sterility testing is noted on Master Formula sheet. Advised to add the table to SOP 2.04 Release Inspections and Testing -it does refer to USP <71> and <85>.*	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	N/A
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3] *Reviewed dispensing records from Life file, nothing dispensed, hence no endotoxin testing*	N/A
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	N/A

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	

STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2]	Yes
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *Following trainings are documented: Repeater pump training, Dry Heat oven use and maintenance training, Steam sterilizer training, Use of bubble point device and Use of pH Meter, Training in surface sampling.* *Reviewed "Aseptic technique and related practices" checklist which was updated to include "Disinfect sterile gloves with sterile 70% IPA every time gloved hands leave and reenter the PEC (ie. operating the repeater pump)."*	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Reviewed documentation of 3 separate gowning and garbing with each GFT for 3 compounders*	Yes
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2]	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *CC PC, HC completed 7/3/24*	Yes
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	Yes
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	Yes
CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	Yes
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1]	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	Yes
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, glovad fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *Per 'Microbiological Air and Surface Monitoring' policy*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *Documented on viable sampling report completed on 3/28/24, and 5/20/24*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *per certifier PASC, last calibrated 10/14/23, due October 2024.*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *Provided trending data from Compounding 360.*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Cultivate TD100 media paddles*	Yes
INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *Trend analysis documented in Compounding 360 aka Pharmacy Stars*	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *per 'Corrective and Preventative Actions' policy*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of egents is in eccordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7] *pPer SOP 2.007 (Cleaning the Sterile Compounding Equipment)*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriataly garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1]	Yes
REUSABLE GARB: Disinfaction procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3]	N/A
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7] *Per SOP 2.007 (Cleaning the Sterile Compounding Equipment), and Compound 360 documentation.*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Facility use TB1 - 3300, Sterile 70% IPA, Sterile and Non-sterile Peridox RTU, and Prompt Plus for cleaning.*	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1]	Yes
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7].	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes

MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1] *Per SOP 2.031 (Movement of Materials – Non Hazardous Drugs), and correctly simulated by Pharmacy technician HC*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7]	
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6]	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *SOP 2.052 reviewed, documentation of receipt maintained in Life File*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *API Manufacturers Semaglutide Lot GIM9820231208, Tirzepatide from Biopeptek*	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1]	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2] *Receipt is documented in Life File*	Yes
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *See bar coded stickers with BUD's*	Yes
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identify, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3] *Added to SOP 2.05 Components used for Sterile Compounded products line 8 -that components are reinspected before use. Advised to add this to the compounding record to demonstrate procedures follow SOP.*	Yes

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview *CSP's are not terminally sterilized at this time. Primary method is filtration.*	Yes
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10] *Sterilization method used prior to submitting for testing of AET,CCT, MS is filtration.*	Yes
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10] *Terminal sterilization is not the present method of sterilization.*	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *Time stamps in Life File provide confirmation that this matches SOP 2.051 for batches made for method suitability testing*	Yes
STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *Trainings documented in Compounding 360*	Yes
CSP Sterilization by Filtration	Yes
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2]	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Training in Compounding 360.* *Inspector observed a bubble point done by Designated Person CC which did not demonstrate essential concepts of pulling air into syringe. Advised to retrain*	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	N/A

CSP Sterilization by Steam *CSP's are not terminally sterilized by steam*	No
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3] *No CSP will be terminally sterilized, however the firm uses BI's and incubates them at 55-60C for 24 hrs after autoclaving bromobutyl rubber stoppers per Mckesson distributor for G.S. BI's.*	N/A
CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3]	Yes
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3] *While CSP's are not sterilized by steam, components that come into contact with the CSP are-Data recorder has 16 PSI documented and temps and time frame of 20 minutes per policy for items such as Bromobutyl rubber stoppers sterilized by steam.*	Yes
CSP Sterilization by Dry Heat *Not terminally sterilizing CSP's by dry heat*	No
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4]	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4]	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4]	N/A

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *Permissible load conditions, considerations for the cycle are now included-as noted in SOP 2.051 (se diagrams and pictures of loads with ECV's)*	Yes
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable contalners and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1]	Yes
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1] *Documented per Eagle Lab Oven Validation using Charles River ECV's to demonstrate a 3.6 log reduction*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is creatad for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1] *Examples of CSP Formulations that are planned for initial testing are:* *Semaglutide/Pyridoxine 2.5mg/5mg-0.5 ml Inj 2ml vials, Tirzepatide/Pyridoxine 15mg/5mg-0.5 ml Inj Lot vials*	Yes
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Per SOP 2.028*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)]	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2] *Pharmacy was able to prepare a sample CR on day of inspection.*	Yes
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)] *Pharmacy was able to provide a sample CR from Life File for Semeglutide/Pyridoxine 2.5mg/5mg-0.5ml Inj Lot ID LG339000345 with a documented 45 day BUD.* *Final yield documented as 225 vials. Also available was a sample batch record Tirzepatide/Pyridoxine 15mg/5mg-0.5ml Inj lot LG339000179, batch yield of 91 vials.*	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Oven cycle and Autoclave cycle is listed as an ingredient in Life File CR for both formulations.*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12]	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Outcome of visual inspection is not clearly stated to include a check for leeks on sample CR for Semeglutide /Pyridoxine 2.5mg/5mg-0.5ml Inj (2ml) states "all vials are clear and non-turbid".* *Per USP<797>, 2022/2023 version, "The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals)."*	No
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *Per SOP 2.04*	Yes
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Not dispensing at this time, per SOP 2.040*	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *Has not compounded for release, just testing*	N/A

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1] *Sonicu -documentation available in Compounding 360 and by graph on paper documents-calibrated 5/24/24*	Yes
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1] *Per USP <797>, 2022/2023 version, "To help ensure that CSP quality is maintained during storage at the compounding facility, personnel must monitor conditions in the storage areas. A controlled temperature area (see {659}) must be established and monitored to ensure that the temperature remains within the appropriate range for the CSP."*	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2] *Per SOP 2.053*	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Per SOP 2.053*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *Per SOP 2.046*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *CAPA Form dated 5/23/24 is still under way to investigate OOS humidity -as recently as 8/27/24 corrections are being made to the HVAC.*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *New Business, nothing dispensed. SOP 2.002 (Adverse Events of Compounded Preparations*	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18] *Has not dispensed for release ye per Life File records. SOP 2.037 (Recall of Compounded Preparations)*	N/A
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1]	N/A
ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18] *New Business*	N/A
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *New Business*	N/A
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	Yes
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20] *Sterility and Endotoxin testing will be done subsequent to compounding for release*	N/A
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20] *New Pharmacy*	N/A

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2]	
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5]	
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1]	
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2]	
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3]	
C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3]	
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2]	
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2]	
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressure in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1]	
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	
SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not usad when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6]	

INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2]	
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterile sterting components are compounded inside a sterile suite. [USP 800 Section 5.3.2]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3]	
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15]	
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15]	
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4]	
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontemineted et least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2]	
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15]	
LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2]	
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated meterials into non-HD areas. [USP 800 Sections 11.1 & 13]	
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	
SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16]	
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	

Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Remarks:

Per Designated Person and PDM, the pharmacy plans on compounding non-hazardous Category 2 drugs per Table 13 of USP <2022>/2023 version.
Inspectors: Mala Cullipher, Charlene Murray

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:9/12/2024

Representative:

Christian Cox

Date:9/12/2024

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
MARCH 21, 2024	PH 25118	143080

QUALIFICATION(S):
Schedule II & IIICommunity Pharmacy

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

EXPIRATION DATE: FEBRUARY 28, 2025

SUPER SAVER PHARMACY #4, LLC
Rush Pharmacy
1977 ALAFAYA TRAIL
SUITE 1121
OVIEDO, FL - 32765

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

SUPER SAVER PHARMACY #4 Rush Pharmacy

License Number: PH35303

Data As Of 9/12/2024

Profession	Pharmacy
License	PH35303
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2025
License Original Issue Date	09/12/2024
Address of Record	1977 ALAFAYA TRAIL SUITE 1121 OVIEDO, FL 32765
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
COX, CHRISTIAN RENFORD	RX DPT MGR/COR/POR	PHARMACIST	59749	04/11/2024
MESSER, BRENT	PHARMACY AFFILIATE	PHARMACY AFFILIATE		09/12/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of

Your license number is PS 59749.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
SEPTEMBER 1, 2021	PS 59749	291730

THE PHARMACIST
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

EXPIRATION DATE SEPTEMBER 30, 2023

CHRISTIAN REMOND COX
3998 KENTSHIRE BLVD
OCOEE, FL 34761

RON DeSANTIS
GOVERNOR

JOSEPH A. LADAPO, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Verification

DISPLAY IS REQUIRED BY LAW

Department of Health

CHRISTIAN RENFORD COX

License Number: PS59749

Data As Of 9/19/2024

Profession	Pharmacist
License	PS59749
License Status	CLEAR/Active
License Expiration Date	9/30/2025
License Original Issue Date	08/14/2019
Address of Record	[redacted] OCOEE, FL [redacted]
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

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Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
SUPER SAVER PHARMACY #4	PDM/CORSUBORDINATE	PHARMACY	35303	4/11/2024
SUPER SAVER PHARMACY #4, LLC	PDM/CORSUBORDINATE	PHARMACY	25118	2/16/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS4162551	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5	RETAIL PHARMACY	05-20-2024

SUPER SAVER PHARMACY #4
DBA RUSH PHARMACY
1977 ALAFAYA TRL STE 1121
OVIEDO, FL 327654522

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

U.S. Department of Justice
REPORT
CHANGES
PROMPTLY
Drug Enforcement Administration

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Super Saver Pharmacy #4 DBA Rush Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH 25118

Physical Address 1977 Alafaya Trail Suite 1121

City Oviedo State FL Zip 32765

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 407 542 0880 Website RushPharmacy.com

Licensing Company Email Licensing@RushPharmacy.com

Section 2: Personal Information

First Christian Middle Renford Last Cox

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State FL Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palm Beach Atlantic University		08/2015 – 05/2019	
Address	City	State	Zip
901 S Flagler Dr	West Palm Beach	Fl	33401
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		08/2010 – 05/15	
Address	City	State	Zip
4202 E. Fowler Ave	Tampa	Fl	33620
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Olympia High School		08 – 08 – 05/10	
Address	City	State	Zip
4301 S Apopka Vineland rd	Orlando	Fl	32835
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
West Orange High School		08/07 – 05/08	
Address	City	State	Zip
1625 Beulah Rd	Winter Garden	Fl	34787
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Apopka High School		08/06 – 05/07	
Address	City	State	Zip
555 Martin St	Apopka	Fl	32712
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23 – Present	[redacted]	Orlando	Fl	[redacted]
05/22 – 05-23		Altamonte Springs	Fl	
03/21 – 03/22		Winter Park	Fl	
08/2001 – 03/21		Ocoee	Fl	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Rush Pharmacy			From - To (MM/YY – MM/YY): 02/24 – Present	
Business Address: 1977 Alafaya Trail Suite 1121	City: Oviedo		State: Fl	Zip: 32765
Phone: 407 542 0880	Title: PIC		Number of Employed Hours: 400	
Description of Duties: Oversee pharmacy operations and compliance				

Business Name: Taylors Pharmacy			From - To (MM/YY – MM/YY): 09/19 – 02/24	
Business Address: 306 S. Park Ave	City: Winter Park		State: Fl	Zip: 32789
Phone: 407 644 1025	Title: Compounding Pharmacist		Number of Employed Hours: 7000	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Christian Cox, certify that as the designated representative for Super Saver Pharmacy #4 DBA Rush Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CC I am at least 21 years of age;
3. CC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christian Cox

Print Name (First, Last)

Christian Cox

Original Signature (electronic, copies or stamps not accepted)

5/8/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christian Cox

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/8/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Seminole

I, Christian Cox, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/10/24

Date

Subscribed and Sworn to before me this 10th day of May, 2024.

Notary Public Signature

JACQUELYN MOHR
Notary Public - State of Florida
Commission # HH 230521
My Comm. Expires Feb 17, 2026
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Super Saver Pharmacy #4, LLC dba Rush Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1977 Alafaya Trail Suite 1121

City Oviedo State FL Zip 32765

Mailing Address (if different from physical address) (SAME ADDRESS)

City _____ State _____ Zip _____

Telephone 407-542-0880 Website www.rushpharmacy.com

Licensing Company Email licensing@rushpharmacy.com

Section 2: Personal Information

First Brent Middle Thomas Last Messer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Jackson State TN Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tennessee High School		1994-1997	
Address	City	State	Zip
	Bristol	TN	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Middle Tennessee State University		1997-1999	
Address	City	State	Zip
	Murfreesboro	TN	
Diploma/Degree obtained, if any			
NA			

School Name		From - To (MM/YY – MM/YY)	
Montreat College		1999-2000	
Address	City	State	Zip
	Black Mountain	NC	
Diploma/Degree obtained, if any			
Na			

School Name		From - To (MM/YY – MM/YY)	
Middle Tennessee State University		2003-2006	
Address	City	State	Zip
	Mufreesboro	TN	
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY	
University Of Memphis		2007	
Address	City	State	Zip
	Memphis	TN	
Diploma/Degree obtained, if any			
Nursing Classes, stopped after 1 year			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2011-2023	[redacted]	Jackson	TN	
2023-present	[redacted]	jackson	TN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name Please See attached sheet			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	X	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question #1 and 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Est 2003	2003	TN	Murfreesboro	Rutherford County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	Murfreesboro City

Reason/Charge
Criminal Impersonation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

While I was in college sometime around 2003 I was arrested for criminal impersonation. My record was expunged.

Original Signature (electronic, copies or stamps not accepted)

Date 9/26/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRENT MESSER
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/26/24
Date

Please have this section completed in the presence of a Notary Public.

State of TN., ss. County of MADISON

I, ~~M Attc~~ BRENT MESSER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/26/24
Date

Subscribed and Sworn to before me this 26th day of SEPT. 2024.

RICK PERRY
Notary Public Signature

COM. EXP. 10-23-24

RICK PERRY STATE OF TENNESSEE NOTARY PUBLIC COUNTY OF

(Seal)

GLM Highland
3811 Turtle Creek Blvd Suite 1440
Dallas, TX 75219

GLM at the Star (Frisco)
3800 Gaylord Pkwy Suite 780
Frisco, TX 75034

GLM Nevada
7455 West Washington Ave Suite 140
Las Vegas, NV 89128

GLM SLC
154 east Myrtle Ave #102
Murray, UT 84107

GLM Indianapolis
10425 Commerce Dr Suite 140
Carmel, IN 46032

BA Medical
3037 West Horizon Ridge Pkwy Suite 110
Henderson, NV 89052

Genesis Telemedicine
3800 Gaylord Pkwy Suite 780
Frisco, TX 75034

Genesis Mothership MSO
3800 Gaylord Pkwy Suite 780
Frisco, TX 75034

Genesis Hendersonville
174 Saundersville Rd, Suite 103
Hendersonville, TN37075

Genesis Weight and Age Management
2000 Glen Echo Rd, Suite 208B
Nashville, TN37215

Cherry Creek Medica Weight Loss & Fort Collins Medical Weight Loss
1325 S. Colorado Blvd Building B Suite 509
Denver, CO 80222

Genesis Aurora Medical Weight Loss
15230 E. Iliff ave Suite A

BTM

Aurora, Co 80014
MBA Properties 51 S Creek dr Jackson, TN 38301
Genesis Franklin 1600 Westgate Circle, Suite 200 Brentwood, TN 37027
Rush Pharmacy 1977 Alafaya Trail #1121 Oviedo, FL 32765
DEFCON 1 Marketing **16 Okeena dr** **Jackson, TN 38305**

All these are current corporations that I am currently the CEO of or a shareholder of. There are some corporations that are not listed that were short lived or closed.

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04025	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Independent/Mail Order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FN9931913 ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: North Coast Medical Supply, LLC dba Advanced Diabetes Supply

Physical Address: 2544 Campbell Place, Suite 150

City: Carlsbad State: CA Zip: 92009

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip: 43017

Telephone: 800-730-9887 Toll Free # (NAC 639.708, NRS 639.23286): 800-730-9887

Fax: 800-503-6280 Contact Email: licensure@cardinalhealth.com

Website: www.northcoastmed.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Fiona Dupuy Hardy

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Thanh K Vu	NV Pharmacist Registration #: 14628
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): ADS Buyer, Inc. (Parent Company of North Coast Medical Supply, LLC dba Advanced Diabetes)

Corporation Name: Cardinal Health Inc. (Ultimate Holding Company)

Mailing Address: 7000 Cardinal Place

City: Dublin State: OH Zip: 43017

Telephone: 614-757-5000 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983 | SEC Registration Number: 721371 | Stock Exchange Symbol: CAH

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director (title) for North Coast Medical Supply, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Keegan David Chamberlain

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/20/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Keegan David Chamberlain hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director (title) for North Coast Medical Supply, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of February, 2025

Notary Public

Michael Williams
Notary Public, State of Ohio
My Commission Expires 05-05-2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keegan David Chamberlain

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

02/20/2025
Date

Board Use Only	Date Received: 2/24/25	Amount: $500 ck 1092253

Nevada BOP Pharmacy Application for
North Coast Medical Supply, LLC dba Advanced Diabetes Supply

List of all Officers and Directors

Officer/Director Name	Title
Robert Evan Schlissberg	President
Keegan David Chamberlain	Director
John Henry Martin Jr.	SVP, Tax
Brent Matthew Withrow	Asst. Treasurer
Anthony F. Alvarez	Secretary

Cardinal Health - Medical Distribution,
Quality & Regulatory Affairs
7000 Cardinal Place
Dublin OH 43017
cardinalhealth.com
614.553.3076 tel

licensure@cardinalhealth.com email

CardinalHealth

Top 4 Corporation Shareholders

Name	Percentage of Ownership
Vanguard Fiduciary Trust Co.	12.65 %
BlackRock Advisors LLC	9.478 %
STATE STREET CORPORATION	5.600 %
Geode Capital Management LLC	2.359 %

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	NORTH COAST MEDICAL SUPPLY, LLC
Entity No.:	202103210235
Registration Date:	01/19/2021
Entity Type:	Limited Liability Company - Out of State
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of December 05, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 272044728

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

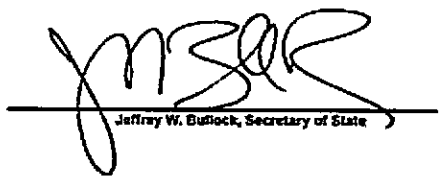
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NORTH COAST MEDICAL SUPPLY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF DECEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NORTH COAST MEDICAL SUPPLY, LLC" WAS FORMED ON THE TWENTY-THIRD DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



4462891 8300

SR# 20244394138

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 205037945

Date: 12-05-24

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy **X** Hospital Pharmacy Clinic Exempt Hospital Wholesaler Hypodermic

Date: 12/12/2024 Inspector: Ben Rustia

Firm: NORTH COAST MEDICAL SUPPLY LLC DBA ADVANCED DIAB Phone: (800) 730-9887

Address: 2544 CAMPBELL PL STE 150 City: CARLSBAD Zip: 92009

Ownership: CORPORATION

Permit #: PHY58055 Permit Exp: 12/1/2025 DEA#: FN9931913 DEA Exp: 10/31/2026

Date of Self Assessment Form: 1/24/2023 Other Permit #: N/A Date of DEA Inventory: 12/9/2024

Hours M-F: 8:30-5:00 Hours Saturday 8:00-12 Noon Hours Sunday: Closed

PIC **FIONA D HARDY** RPH43870 Administrator

RPH Consultant

Staff RPH Name:	License #:
AMANDA C BROEDELL	RPH77148
CARRIE D HUSTON	RPH59231
HANH T DANG	RPH57286
KATHERINE A NORRIS	RPH77082
PATRICK J TRACY	RPH83001
SU J KONG	RPH51746
VANITA BHAILALB KOTHIY	RPH71539
HUONG L NGUYEN	RPH81094
PARVA RAHMANIAN	RPH84359
IRIS E STERBA	RPH65503
THANH K VU	RPH51078

Staff Name:	License #:
BIANCA H PARTIDA	TCH162787
CYNTHIA A DORANTES CRUZ	TCH170383
HEATHER L GAMBLES	TCH177596
JADEN B PETKOV	TCH193837
JAIME S MARTINEZ MERIN	TCH150933
JAVIER JUAREZ	TCH181313
MALEKA R MARCH	TCH177574
MARIA A OROZCO	TCH198459
MARISOL MORALES	TCH196836
MEGUMI MCCLURE	TCH128915
MICHELLE A GUERRERO R	TCH197282
NATALEE GARCIA	TCH192531
SADIE V MACIAS	TCH175855
SHELBY D VAN ENGEN	TCH116863
VEATRIZ ROJAS APARICIO	TCH167044

Inspector Remarks:

Routine inspection of closed door pharmacy located in a building within commercial park.
No compounding.
Primarily dispense diabetic supplies and insulin.
Pharmacy receives email notification from the Board at northcoastmed.com
Licensed in 48 states and DC.
Licensed by CA State Food and Drug
Accredited by URAC, NABP
Licenses and Notice to consumer poster, and language poster posted in public view:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

INSPECTION REPORT

Self-Assessments: in place and reviewed.

Policies and Procedures in place and reviewed:

- Quality Assurance – medication error reporting;
- Impaired employee/Theft and diversion;
- Technician Job Description;
- Interpretive services

Controlled Substances:

- Registered with the DEA but no controlled substances on hand;
- Biennial inventory maintained.
- CURES Transmitting weekly.
- Quarterly Reconciliation of Schedule II and yearly reconciliation of alprazolam, tramadol, and promethazine with codeine: maintained

Drug acquisition and disposition:

- Manufacturers and wholesalers: Abbott Diabetes Care, Ascencia Diabetes Care, Beta Bionics, Dexcom, Insulet, Intrapump Infusion Systems, McKesson, Medtronic MineMed, Tandem Diabetes Care.
- Reverse distributor: Inmar.

Facility:

- Secure, no security cameras in place.
- Orderly, organized, shelves clean, medications not stored on the floor.
- Refrigerator and freezer: clean; Temperature: monitored electronically and manually logged. pharmacist notified when temperature excursions occur.
- Sink with hot and cold running water.
- Accessible restroom.
- ADDS: None
- Return Drug Box: None

Storage of records:

- Offsite, waiver 228615 issued.
- Within pharmacy.

Staff:

- Ratio of pharmacist and technician during the inspection: compliant
- ID badges worn by Pharmacist and technicians.

Prescription:

- Prescription labels conforms to patient centered requirements, with physical description of drug.

Consultation:

- Consultation: notification printed on auxiliary label. Pharmacist available Monday to Friday 8:30 to 5:00 PM and 8:00 AM to 12 Noon on Saturdays.

Other Clinical Services:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

None

Educational topics Discussed:

- Board provides CE for Law and Ethics and DEA trainings. check Board website for training schedule.
- Reminder of the requirement for Pharmacist, Interns and Pharmacy technicians to submit email address to Board.
- Board Publication The Script: Available at the Board website.
- Renewal of license though the Board website.

DISCUSSION:

None

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Fiona Hardy

Pharmacist (print) FIONA HARDY

Inspector (sign) B. Russell

Inspector (print) B. Russell

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 58055
Receipt No. 42770249

Valid Until: 12/1/2025

NORTH COAST MEDICAL SUPPLY LLC DBA
ADVANCED DIABETES SUPPLY
2544 CAMPBELL PL STE 150
CARLSBAD, CA 92009-1768

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

The official status of this license can be verified at www.pharmacy.ca.gov

This permit is valid only at the address shown.

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

CALIC100.RENWALR.10072024.48021.SEQID9387

NORTH COAST MEDICAL SUPPLY LLC DBA ADVANCED
DIABETES SUPPLY
2544 CAMPBELL PL STE 150
CARLSBAD, CA 92009-1768 9387

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58055

NAME: NORTH COAST MEDICAL SUPPLY LLC DBA ADVANCED DIABETES SUPPLY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

2544 CAMPBELL PL STE 150
CARLSBAD CA 92009
SAN DIEGO COUNTY

ISSUANCE DATE

DECEMBER 31, 2020

EXPIRATION DATE

DECEMBER 1, 2025

CURRENT DATE / TIME

FEBRUARY 6, 2025
1:34:37 PM

LICENSE RELATIONSHIPS

NAME: HARDY, FIONA DUPUY

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 43870 **PRIMARY STATUS:** CLEAR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN9931913	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
5	RETAIL PHARMACY	09-13-2023

NORTH COAST MEDICAL SUPPLY, LLC
DBA ADVANCED DIABETES SUPPLY
2544 CAMPBELL PL STE 150
CARLSBAD, CA 920091768

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN9931913	10-31-2026	$888

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NORTH COAST MEDICAL SUPPLY, LLC
DBA ADVANCED DIABETES SUPPLY
2544 CAMPBELL PL STE 150
CARLSBAD, CA 920091768

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Form DEA-223 (9/2016)

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Specialty HIV/AIDS

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pharmacy4Humanity DBA AHF Pharmacy

Physical Address: 18421 S. Main Street,

City: Carson State: CA Zip: 90248

Mailing Address (if different from physical address): 19300 S. Hamilton Ave., STE 110-111,

City: Gardena State: CA Zip: 90248

Telephone: 3107710562` Toll Free # (NAC 639.708, NRS 639.23286): 8669936337

Fax: 3107710621 Contact Email: PharmacyOperations@ahfrx.org

Website: www.aidshealth.org

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Hannah Suh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22132

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Name: _____ NV Pharmacist Registration #: _____

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): AIDS Healthcare Foundation

Corporation/Organization Name: Pharmacy4Humanity

Mailing Address: 19300 S. Hamilton Ave., STE 110-111,

City: Gardena, State: CA Zip: 90248

Telephone: 3109996089 Email: PharmacyOperations@ahfrx.org

Contact Person Name: Michelle Ascheri

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Pharmacy Officer (title) for AHF Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kenneth Scott Carruthers

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

05/17/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Kenneth Scott Carruthers hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer (title) for AHF Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Kenneth Scott Carruthers

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

See attached certificate

Notary Public

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 17th day of May, 2024, by Kenneth Scott Carruthers,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ANTOANETA ANGELOVA GEORGIEVA
Notary Public - California
Los Angeles County
Commission # 2345096
My Comm. Expires Feb 3, 2025

(Seal) Signature

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Scott Craruthers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/17/2024

Date

Board Use Only	Date Received: 8/8/24	Amount: $500-Ck 41935

AHF PHARMACY

11/7/2024

AHF corporate officers

Name	Title	Address
Michael Weinstein	President	6255 W. Sunset Blvd., FL 21, Los Angeles, CA 90028
Peter Reis	Sr. Vice President	6255 W. Sunset Blvd., FL 21, Los Angeles, CA 90028
Lyle Honig Mojica	CFO	6255 W. Sunset Blvd., FL 21, Los Angeles, CA 90028
Kenneth Scott Carruthers	Chief Pharmacy Officer; Senior Manager	6255 W. Sunset Blvd., FL 21, Los Angeles, CA 90028

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	AIDS HEALTHCARE FOUNDATION
Entity No.:	1589471
Registration Date:	06/10/1987
Entity Type:	Nonprofit Corporation - CA - Public Benefit
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 25, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 204290221

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pharmacy4Humanity DBA AHF Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 18421 S. Main Street,

City: Gardenba State: CA Zip: 90248

Mailing Address (if different from physical address): 19300 S. Hamilton Ave., STE 110-111,

City: Gardena State: CA Zip: 90248

Telephone: 310-771-0562 Website: www.aidshealth.org

Licensing Company Email: PharmacyOperations@ahfrx.org

Section 2: Personal Information

First: Hannah Middle: Last: Suh

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Gardena State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Keck Graduate Institute - School of Pharmacy		09/15 - 05/19	
Address	City	State	Zip
535 Watson Dr.	Claremont	CA	91711
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
California State Polytechnic University		08/07 - 06/10	
Address	City	State	Zip
3801 W Temple Ave	Pomona	CA	91768
Diploma/Degree obtained, if any			
Bachelor of Science, Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Fullerton College		08/04 - 05/07	
Address	City	State	Zip
321 E Chapman Ave	Fullerton	CA	92832
Diploma/Degree obtained, if any			
Associate's Degree, Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Sunnyhills High School		08/00 - 06/04	
Address	City	State	Zip
1801 Lancer Way	Fullerton	CA	92833
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/21 - present	[redacted]	Cypress	CA	[redacted]
01/18 - 11/21		Anaheim	CA	
11/15 - 12/17		Brea	CA	
01/12 - 10/15		Anaheim	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
AIDS Healthcare Foundation (AHF) Pharmacy			03/20 - Present	
Business Address		**City**	**State**	**Zip**
19300 S Hamilton Ave suite 170		Gardena	CA	90248
Phone	**Title**		**Number of Employed Hours**	
310-771-0562	Pharmacy Director		9,320 +	

Description of Duties

Strategic Support Team Pharmacist (March 2020 – May 2020), Central Refill Center Clinical Pharmacist (June 2020 – August 2022), Assistant Pharmacy Director (September 2022 – March 2024), Pharmacy Director (April 2024-present)

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			06/19 – 02/20	
Business Address		**City**	**State**	**Zip**
14885 Telegraph Rd		La Mirada	CA	90638
Phone	**Title**		**Number of Employed Hours**	
562-777-3405	Graduate Intern Pharmacist		2,040	

Description of Duties

Consulted with patients regarding the proper use of medications, potential allergies, adverse drug reactions, and side effects to ensure the safety of the patient. / Administered immunizations, performed immunization screening

Business Name			From - To (MM/YY – MM/YY)	
Fullerton Medical Pharmacy			01/18 – 05/19	
Business Address		**City**	**State**	**Zip**
1401 S Brookhurst Rd #101		Fullerton	CA	92833
Phone	**Title**		**Number of Employed Hours**	
714-992-4908	Intern Pharmacist		1,920	

Description of Duties

- Performed blood pressure and blood glucose screenings and provided patient education.
- Increased patient compliance through patient care quality calls.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Hannah Suh, **certify that as the designated representative for**

Pharmacy4Hymanity DBA AHF Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HS I am at least 21 years of age;
3. HS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hannah Suh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/29/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hannah Suh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/29/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Please see attached certificate

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 29th day of July, 2024, by Hannah Suh

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ANTOANETA ANGELOVA GEORGIEVA
Notary Public - California
Los Angeles County
Commission # 2345096
My Comm. Expires Feb 3, 2025

(Seal) Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Pharmacy4Humanity DBA AHF Pharmacy

Physical Address: 18421 S. Main Street,

City: Carson State: CA Zip: 90248

Mailing Address (if different from physical address): 19300 S. Hamilton Ave., STE 110-111,

City: Gardena State: CA Zip: 90248

Telephone: 310-999-6089 Website: www.aidshealth.org

Licensing Company Email: PharmacyOperations@ahfrx.org

Section 2: Personal Information

First: Michael Middle: Last: Weinstein

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Los Angeles State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty: _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
15 Years	[redacted]	Los Angeles	CA [redacted]	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AIDS Healthcare Foundation			1984- Present
Business Address	**City**	**State**	**Zip**
6255 Sunset Blvd., 21ST FL,	Los Angeles	CA	90028
Phone	**Title**		
323-860-5200	President		
Description of Duties			
Oversees high level functions of organization			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Weinstein

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/23/24

Date

Please have this section completed in the presence of a Notary Public.

See attached.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

Applicant's initials _____

CALIFORNIA JURAT GOVERNMENT CODE § 8202

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd (Date) day of April (Month), 2024 (Year), by

(1) Michael Weinstein

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Pharmacy4Humanity DBA AHF Pharmacy

Physical Address 18421 S. Main Street

City Carson State CA Zip 90248

Mailing Address (if different from physical address) 19300 S. Hamilton Ave., STE 110-111,

City Gardena State CA Zip 90248

Telephone 310-999-6089 Website www.aidshealth.org

Licensing Company Email PharmacyOperations@ahfrx.org

Section 2: Personal Information

First Lyle Middle Honig Last Mojica

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Los Angeles State CA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials LM

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kansas State University		01/88-12/92	
Address	**City**	**State**	**Zip**
Manhattan	Manhattan	KS	66506
Diploma/Degree obtained, if any			
BS Finance/ Accounting			

School Name		From - To (MM/YY – MM/YY)	
Wamego High School		8/84-6/88	
Address	**City**	**State**	**Zip**
801 Lincoln Ave	Wamego	KS	66547
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/22 - Present	[redacted]	Los Angeles	CA	[redacted]
5/19 - 4/22		North Hollywood	CA	
5/15 - 5/19		Los Angeles	CA	
5/12- 5/15		Toluca Lake	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AIDS Healthcare Foundation			04/02 - Present	
Business Address		**City**	**State**	**Zip**
6255 W. Sunset Blvd., FL 21,		Los Angeles	CA	90028
Phone	**Title**			
818-209-2294				
Description of Duties				
Finance/ Accounting				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1995	1995	CA	Los Angeles	Los Angeles
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		County of Los Angeles		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Lyle Honig Mojica				
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lyle Honig Mojica

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

see attached..

(Seal)

Applicant's initials

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 23rd day of April, 2024, by Lyle Honig Mojica,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ALEXANDER BEVERLY
Notary Public - California
Los Angeles County
Commission # 2460044
My Comm. Expires Aug 20, 2027

(Seal) Signature Alexander Beverly

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Pharmacy4Humanity DBA AHF Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 18421 S. Main Street,

City: Carson State: CA Zip: 90248

Mailing Address (if different from physical address): 19300 S. Hamlton Blvd., STE 110-111,

City: Gardena State: CA Zip: 90248

Telephone: 310-999-6089 Website: www.aidshealth.org

Licensing Company Email: PharmacyOperations@ahfrx.org

Section 2: Personal Information

First: Kenneth Middle: Scott Last: Carruthers

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Gardena State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/1958 – 06/1962	
Address: 3551 Trousdale Parkway	City: Los Angeles	State: CA	Zip: 9007
Diploma/Degree obtained, if any: Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
San Diego State University		09/1956 – 06/1958	
Address: 5500 Campanile Dr.	City: San Diego	State: CA	Zip: 92182
Diploma/Degree obtained, if any: BS - Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Mission Bay High School		09/1953 – 06/1956	
Address: 2475 Grand Ave.	City: San Diego	State: CA	Zip: 92109
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2022 - Current	[redacted]	Seal Beach	CA	[redacted]
01/1981 - 07/2022	[redacted]	Temple City	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's Initials: KSC

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AIDS HEALTHCARE FOUNDATION			06/2004 CURRENT
Business Address	**City**	**State**	**Zip**
6255 W. SUNSET BLVD. 21ST FLOOR	LOS ANGELES	CA	90028
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Scott Carruthers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/06/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

See attached certificate

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

Applicant's initials KSC

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 6th day of May, 2024, by Kenneth Scott Carruthers,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ANTOANETA ANGELOVA GEORGIEVA
Notary Public - California
Los Angeles County
Commission # 2345096
My Comm. Expires Feb 3, 2025

(Seal) Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Pharmacy4Humanity DBA AHF Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 18421 S. Main Street,

City: Carson State: CA Zip: 90248

Mailing Address (if different from physical address): 19300 S. Hamilton Ave., STE 110-111,

City: Gardena State: CA Zip: 90248

Telephone: 3109996089 Website: www.aidshealth.org

Licensing Company Email: pharmacyoperations@ahfrx.org

Section 2: Personal Information

First: Peter Middle: Last: Reis

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Los Angeles State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)				
From - To (MM/YY – MM/YY) 14 Years	[redacted]	City Studio City	State CA\	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AIDS Healthcare Foundation			
Business Address	**City**	**State**	**Zip**
6255 W. Sunset Blvd.,	Los Angeles	CA	90028
Phone	**Title**		
3238605200	Senior Vice President		
Description of Duties			
Senior Vice President in charge of overseeing Financial and Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Reis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

see attach

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 15 day of May, 2024, by Peter Reis,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

MARISA NILCHAVEE
Notary Public - California
Los Angeles County
Commission # 2471525
My Comm. Expires Nov 13, 2027

(Seal)

Signature

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 2/11/2025 Inspector: Suzy Patell

Firm: PHARMACY4HUMANITY DBA AHF PHARMACY Phone: (310) 374-6284

Address: 18421 S MAIN ST City: GARDENA Zip: 90248

Ownership: LLC

Permit #: PHY59517 Permit Exp: 6/1/2025 DEA#: FP4359508 DEA Exp: 3/31/2027

Date of Self Assessment Form: 11/9/2024 Other Permit #: N/A Date of DEA Inventory: 11/14/2024

Hours M-F: 24Hr Hours Saturday 24Hr Hours Sunday: 24Hr

PIC **HANNAH E SUH** RPH81906 Administrator

RPH Consultant

Staff	RPH Name:	License #:
	JOHN A STAPF	RPH70945
	BRIAN H LEBEDINSKI	RPH80015
	SOHYUN KIM	RPH68948
	YANNICK NGA	RPH89544
	STEPHANIE F MOY	RPH59971
	ALBERT M CHEN	RPH73869
	EDUARDO L VILLARUZ III	RPH85911
	CHARLES W WALKER JR	RPH36998
	SOYOUNG KIM	RPH88535
	LIONEL V ISHIKAWA	RPH81913
	SARAH A CHEHABI	RPH65329
	KAREN T LY	RPH81986

Staff Name:	License #:
ADRIANE S REMOLIN	TCH155227
ALEJANDRO PRECIADO JR	TCH173926
ANEL JIMENEZ	TCH168092
ANEX L CORDERO	TCH77182
CHRISTINE K NGUYEN	TCH159016
DENISE T PEREZ	TCH85580
ELIZABETH A MORALES	TCH62646
FARHANA A AHMED	TCH185285
FELICIA A SMITH	TCH44892
GIANNA LONG	TCH1551
JAE JEONG- PHARMACY POR	TITLE
JAZMIN PONCE MORAL	TCH194590
JENNIFER R LAGEMAN	TCH180570
JESSICA A MARIN	TCH151176
KATHERINE E WOOD	TCH49863
KAYLEE F CRUZ	TCH162034
KEVIN SOUVANNARITH	TCH173266
LUSI ARTEAGA	TCH131749
MARCELO D RODRIGUEZ	TCH154014
NGOC EPPERSON	TCH76870
PEGGY A BELL-MOORE	TCH57130
RAYNA L MEGGS	TCH109343
RODRIGO A RODRIGUEZ	TCH133038
ROSSVINMAE L BAIDIANGO	TCH134133

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INSPECTION REPORT

SANDY B ALBARRAN	TCH173053
SU YEON SHIN	TCH193384
VALERIE VASQUEZ	TCH169159
VANESSA GARCIA	TCH154560

Inspector Remarks:

Inspection conducted with Inspector Huy Do.
Closed door outpatient pharmacy, run by a non-profit foundation, dispensing only refills of medications to ambulatory patients via mail/delivery and also for pick up at home pharmacy locations. Inspection conducted with PIC Hannah Suh, RPHs John Stapf and Karen Ly. This new location expands operational capacity- pharmacy is currently filling about 5000Rxs/day and is licensed in 19 states, including CA, the pharmacy currently fulfils at 32 locations. Operations and inventory moved here is November 2024; DOB for PHY 59417 at 19300 S Hamilton Ave #170/180,has been filed with the Board. Suite150 for Pharmacy Performance and customer care center is still located at 19300 S Hamilton Ave, Gardena,
Current operations: Fills all medications, except CIIs; specializes in adherence packaging and HIV meds.
Location: The building at 18421 S Main Street is a single storey building with two walled areas- the front is occupied by AHF Pharmacy; the back is occupied by Gentle Giant Moving. PIC Suh educated on only licensing the pharmacy areas and change of permit requested within 72 hours.

AUTOMATION:
Reviewed and toured the pharmacy.
Pharmacy contains three different dispensing areas (compliance/adherence packs, manual fill, and automated vial dispensing), packaging area, and sorting/delivery area.
The pharmacy uses Coreflex by Parata- a production line/logistics software program which interfaces with McKesson Enterprise Pharmacy Operating System and is connected to multiple home pharmacies across the nation. Each fulfilment is placed into an automated filling system w/RFID tagged tote scanned with barcodes to route and ensure for accuracy. This location has access to patient profile via common electronic file; receives labels for fulfilment from home pharmacies- new ones are filled by home pharmacy; refills filled by this location and mailed/delivered to patient or FedExed/delivered to home pharmacy for patient pick up. Rx orders are received by home pharmacy and processed there. Filling, product verification, packing and shipping performed at this location.
Parata ATP ADDS devices is used for adherence packaging in Calendar blister packs- multi med packs. Reviewed process for replenishing and verification from the pharmacist. Discussed packaging protection from light. 45 day expiration date, reviewed patient centered labeling. Originating pharmacy is displayed on the label. Automated InspectRx for pouch scanning and identification of broken/missing pills reviewed. RPH still visually checks each pouch.
Synmed Ultra ADDS devices used for adherence packaging in Go Packs (bubble). Discussed packaging protection from light. 45 day expiration date, reviewed patient centered labeling. Originating pharmacy is displayed on the label.
Pharmacist reviewed packaging manually based on descriptions printed on label and/or stock images taken from the package.
Parata Max2Plus ADDS devices is a cabinet style ADDS used to dispense medication into vials. The devices counts, labels, and caps the prescription.
Reviewed process for replenishing and verification from the cannisters. Currently, TCH scans the stock bottle, cannisters, and updates the lot/expiration dates. RPH is not involved with reviewing the replenishing process. Recommended and suggested updating practices with verification process. Reviewed labels and found "generic for" wording ~~did not contained~~ the name of the brand used. No photographs taken, RPH visually verifies vials.
Hazardous drugs were placed in the ADDS devices. Educated to reviewed USP 800 on handling and placing drugs into the device and to have assessment of risk available.
Policy and procedures related to the ADDS are in process. Educated to have p/p readily available to address replenishment, maintenance, accuracy, and quality assurance.

Workflow: Reviewed process from originating pharmacy orders to fulfilment center. New prescriptions are filled at the originating pharmacy. Refills are filled at the central fill fulfilment location. Packages are sorted based on location. Prescriptions are sorted and placed into individual mailer packages. Once received at the home pharmacy, the packages

INSPECTION REPORT

may remain intact with a barcode scanned at the point of sale. The originating pharmacy does not verify the product again.

Shipping: cold chain for refrigerated or temp controlled/shipping across states/Overnight were discussed.

The pharmacy also services 340b medications. Software is used to sort and manage inventory from the covered entity and contracted pharmacies. Discussed practice for drugs not picked up and process for handling medications not used once received at the originating pharmacy. Per PIC, drugs placed in compliance packs are destroyed and managed by the originating pharmacy. For prescriptions filled in vials, the drugs are returned to the home pharmacy and added to their own inventory. All records and chain of custody are documented electronically.

Consultation: Reviewed written notice for consultation. Home Pharmacy phone number available and call center number is available and is routed to the central fill pharmacy which is available 24 hours.

Cleaning, Maintenance: Completed daily, weekly, and routinely. The ADDS devices are maintained routinely by the manufacturer. Daily and weekly cleaning are performed by the pharmacy staff.

Medication error reporting: Reviewed. All incidents/complaints are first addressed by the home pharmacy. Once reviewed and investigated, based on the type of error, the responsible pharmacy will complete the QA report. All QA reports are linked between the originating pharmacy and the central fill pharmacy for access between the two locations, The originating pharmacy will reach out to the customer and/or prescriber to complete the incident report. Reviewed recent reports, 2 incidents occurred from opening in November 2024.

Routine Inspection Retail Pharmacy
REVIEWED:
Notice to Consumer, Original License and Renewal, and DEA: available. Location discussed w/PIC Suh.
Sink Hot/Cold Water and eyewash available. Pharmacy is organized and clutter free.
Temperatures - Refrigerator Temperature-paper and electronic. Continuous monitoring w/notification via Dickson.
Scanning for outdated drugs performed 6 months out on a rotating schedule.
CURES: transmitted daily automatically, w. notification from Bamboo received as needed.
Email Alerts: all RPHs and TCHs signed up, per PIC.
Security: keys, card access (assigned per level and schedule), alarm discussed w/PIC.
Policy / Procedure - Technician Job Description, Theft/Impairment/Diversion, Quality Assurance- P&Ps available. Inventory reconciliation P&Ps discussed for actual procedures used during inventory reconciliation and accounting of inaccurate counts within Parata.
Labels: physical description of pills available; compliance with CCR 1707..5 reviewed. PIC to ascertain availability of 'generic for' for on label.
Prescription Orders: none at this location; Order entry, DUR, allergy review, consultation performed by home pharmacy- offer of consult provided on each order sent out from this location, on invoice.
Invoices -scheduled and dangerous drug invoices stored separately; RPH signs and receives drugs from wholesaler.
Offsite Waiver: none.
DEA Inventory –available from November move. Inventory reconciliation performed by automated Coreflex software system- PIC educated on manual portions inherent within the automated reconciliation.
Name Tags: worn- part of access badge. Typical staffing is 9 RPHs: 13-19 TCHs.
WLS: mainly Cardinal; some ABC; Anda; some ordering from manufacturers.
RD: Pharmalink and Allied.
Computer: McKesson Enterprise Pharmacy Operating System. Coreflex is fulfillment system.
Compounding: no compounding

EDUCATION: Topics guidance discussed.

1. Consultation requirements for RX mail/delivery- RPH within 10min or schedule call within 1 hour- minimum 6 days and 40 hrs. per week- Effective 10/1/20
2. BPC 4113 – PIC authority to make staffing decisions

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INSPECTION REPORT

3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
4. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.
5. New PIC training available on Board website
6. Board CE webinars and DEA trainings. Board provided Law & Ethic CE requirements.
7. New Script newsletter available on BOP website
8. USP 800 on hazardous drugs
9. CCR 1711(f): Notification of errors related to the use of ADDS. All errors related to the use of the unlicensed ADDS must be reported at the time of renewal can be emailed at ADDS@dca.ca.gov

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

DISCUSSION:
Please provide the following to Inspector Patell at suzy.patell@dca.ca.gov, no later than 2/14/2025:
1. Email the Board and CC me, with a Change or Permit application to exclude Gentle Giant Moving from license address for the pharmacy. Please provide a map of the facility/building for reference.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Hannah Suh

Pharmacist (print) Hannah Suh

Inspector (sign) Suzy Patell/ Hm PO

Inspector (print) Suzy Patell/ Hm PO

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59517

NAME: PHARMACY4HUMANITY DBA AHF PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

18421 S MAIN ST
GARDENA CA 90248
LOS ANGELES COUNTY

ISSUANCE DATE

JUNE 3, 2024

EXPIRATION DATE

JUNE 1, 2025

CURRENT DATE / TIME

FEBRUARY 18, 2025
9:33:5 AM

LICENSE RELATIONSHIPS

NAME: SUH, HANNAH EURIM

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 81906 **PRIMARY STATUS:** CLEAR

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Aurora Specialty Pharmacy

Physical Address: N93W14575 Whittaker Way

City: Menomonee Falls State: WI Zip: 53051

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 262-253-3000 Toll Free # (NAC 639.708, NRS 639.23286): 847-409-0148

Fax: 262-253-3001 Contact Email: Thomy.Singh@aah.org

Website: aurorapharmacy.org/mail

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Thomy Singh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24176

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Thomy Singh	NV Pharmacist Registration #: 24176
Name: Gurvir Dosanjh	NV Pharmacist Registration #: 24342
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Wisconsin

Parent Company (if any): Aurora Health Care Ventures, Inc.

Corporation/Organization Name: Aurora Pharmacy, Inc.

Mailing Address: 750 W. Virginia St.

City: Milwaukee State: WI Zip: 53204

Telephone: 414-861-9228 Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Aurora Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Thomy Singh

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

01-15-2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Thomy Singh hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Aurora Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

NOTARY PUBLIC Lori Jean Re STATE OF WISCONSIN

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15th day of January, 2025

Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomy Singh

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

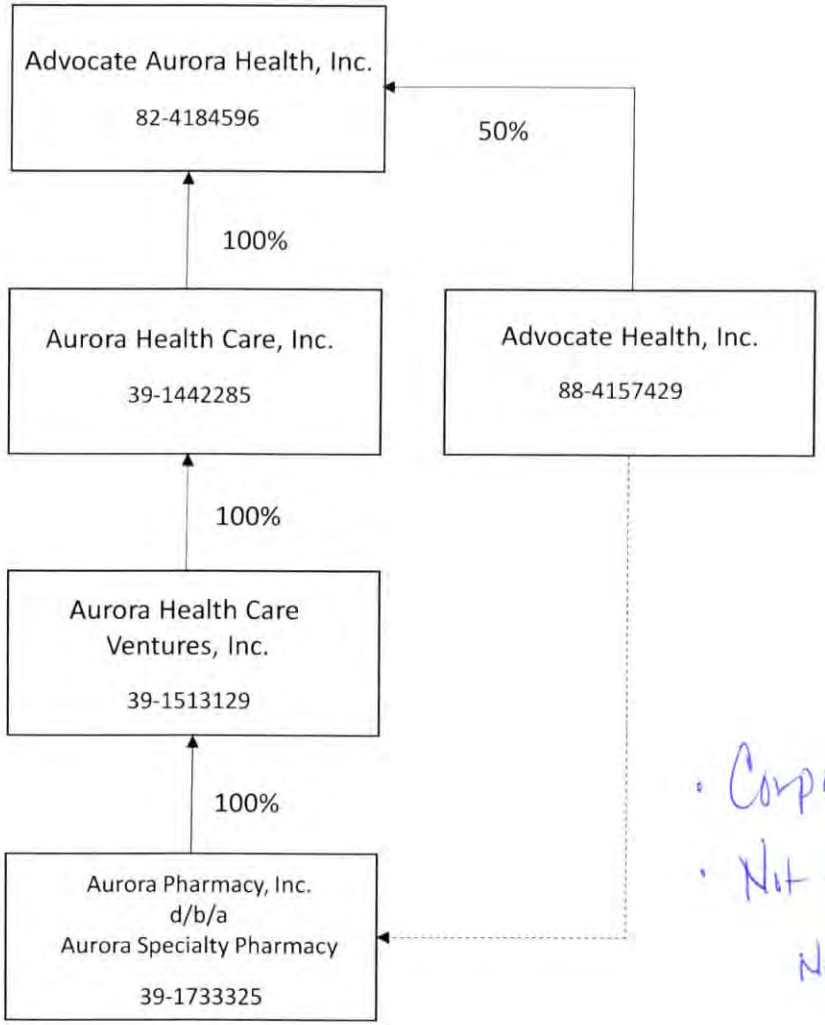
01-15-2025

Date

Board Use Only	Date Received: 2/20/25	Amount: $500-cc

Aurora Pharmacy, Inc.

Directors	Director Election Date	Officers	Title	Officer Election Date
Collin Lane	Effective 1/1/24 (by written consent signed 1/27/24)	Collin Lane	Chairman	Effective 1/1/24 (by written consent signed 1/27/24)
Nan Nelson		Collin Lane	President	2/15/2024
Rachelle Hart		Rachelle Hart	Secretary	2/15/2024
		Nan Nelson	Treasurer	
		Katherine Ketner	Assistant Secretary	2/15/2024
		Michael Kerns	Assistant Secretary	
		Sue Dwyer	Assistant Treasurer	2/15/2024
		Rachel Halverson	Assistant Treasurer	2/15/2024
		Brad Clark	Assistant Treasurer	2/15/2024
		Carrie Donovan	Assistant Treasurer	
		Michael Volante	Assistant Treasurer	
		Robin Stoen	Assistant Treasurer	



Legend:

= Ownership (arrow pointing to owner; percentage as indicated)

= Managing control (arrow pointing to entity controlled)

= Corporation

- Corporation
- Not Publicly traded

No Shareholders

United States of America

State of Wisconsin

DEPARTMENT OF FINANCIAL INSTITUTIONS

Division of Corporate & Consumer Services

To All to Whom These Presents Shall Come, Greeting:

I, Craig Heilman, Administrator of the Division of Corporate and Consumer Services, Department of Financial Institutions, do hereby certify that

AURORA PHARMACY, INC.

is a domestic corporation or a domestic limited liability company organized under the laws of this state and that its date of incorporation or organization is May 15, 1992.

I further certify that said corporation or limited liability company has, within its most recently completed report year, filed an annual report required under ss. 180.1622, 180.1921, 181.0214 or 183.0212 Wis. Stats., but that it has not filed a statement or articles of dissolution.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department on September 12, 2024.

CRAIG HEILMAN, Administrator
Division of Corporate and Consumer Services
Department of Financial Institutions

DFI/Corp/33

To validate the authenticity of this certificate

Visit this web address: https://apps.dfi.wi.gov/apps/ccs/verify/

Enter this code: **398124-47DC80D2**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Aurora Specialty Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: N93W14575 Whittaker Way

City: Menomonee Falls State: WI Zip: 53051

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 262-253-3000 Website: aurorapharmacy.org/mail

Licensing Company Email: Thomy.Singh@aah.org

Section 2: Personal Information

First: Thomy Middle: Last: Singh

Alias(es, nicknames, name changes, etc.): Navtej Singh

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Menomonee Falls State: WI Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University Of Wisconsin Madison School of Pharmacy			09/10 - 05/14	
Address		**City**	**State**	**Zip**
777 Highland Ave		Madison	WI	53705
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			**From - To (MM/YY – MM/YY)**	
University Of Wisconsin Milwaukee			09/04 - 12/09	
Address		**City**	**State**	**Zip**
3203 N Downer Ave		Milwaukee	WI	53211
Diploma/Degree obtained, if any				
Bachelors of Science - Microbiology and Biochemistry				
School Name			**From - To (MM/YY – MM/YY)**	
Rufus King High School			09/99 - 06/03	
Address		**City**	**State**	**Zip**
1801 W. Olive St		Milwaukee	WI	53209
Diploma/Degree obtained, if any				
High School Degree				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
08/2016-Current		Milwaukee	WI	
From - To (MM/YY – MM/YY)		City	State	
08/2014-Current		Milwaukee	WI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Aurora Specialty Pharmacy			07/14 - present
Business Address	**City**	**State**	**Zip**
N93W14575 Whittaker Way	Menomonee Falls	WI	53051
Phone	**Title**		**Number of Employed Hours**
262-253-3000	Pharmacy Clinical Coordinator/Pharmacist in Charge		40 hr/week
Description of Duties			
-Maintain pharmacy compliance with all rules, laws, standards and regulation set forth by various federal, state, local, and accreditation bodies. Perform clinical pharmacist duties with regards to prescription review and verification when needed.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Thomy Singh, **certify that as the designated representative for**

Aurora Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TS I am at least 21 years of age;
3. TS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Thomy Singh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01-15-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomy Singh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01-15-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Wisconsin, ss. County of Brown

I, THOMY SINGH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01-15-2025

Date

Subscribed and Sworn to before me this 15th day of January.

Notary Public Signature

NOTARY PUBLIC
Lori Jean Re
STATE OF WISCONSIN

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1420370		**Inspection Information**
Legal Business Name:	Aurora Pharmacy, Inc.	**Conference Call Date:**	N/A
Doing Business As (DBA):	Aurora Specialty Pharmacy	**Start Time: 24-hour format (13:00)**	N/A
Address:	N93 W14575 Whittaker Way	**End Time: 24-hour format (13:00)**	N/A
City:	Menomonee Falls	**Onsite Inspection Date(s):**	11/18/2024 - 11/19/2024
State:	Wisconsin	**Start Time(s): 24-hour format (13:00)**	09:00 / 09:00
Zip Code:	53051	**End Time(s): 24-hour format (13:00)**	16:30 / 10:30
Telephone number:	2622533001	**Inspector Name(s):**	Reginal Bellamy
Toll free number:	N/A	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	N/A	**Observer Name/Affiliation (if applicable):**	N/A
Website:	aurora.org/pharmacy	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 47.10, 57.00, 93.00

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:00	18:00	
Tuesday	8:00	18:00	
Wednesday	8:00	16:00	
Thursday	8:00	16:00	
Friday	8:00	16:00	
Saturday	9:00	13:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Thomy Singh	thomy.singh@aah.org	851861
Nonsterile Designated person(s)	N/A	N/A	N/A
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Thomy Singh	PIC/Pharmacy Clinical Coordinator	Y
2			
3			
4			
5			
6			
7			
8			
9			
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Wisconsin Pharmacy Examining Board	Aurora Specialty Pharmacy	Pharmacy	9438-42/ Exp. 5/31/2026
Drug Enforcement Administration	Aurora Specialty Pharmacy	DEA (Facility)	FA6482943/ Exp. 6/30/2025

Inspector Notes: List states in which Non-Resident licenses are held AL, AK, CO, DE, FL, GA, HI, ID, IL, KS, KY, LA, ME, MD, MI, MA, MN, MS, MO, MT, NE, NH, NJ, NC, NY, ND, SD, OH, OK, OR, PA, RI, SC, TN, TX, VT, VA, WV, WY

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01-GP39	Temperature logs
Doc02-GP61	Label

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	X
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	X
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	19140	Total Pharmacists:	41
Nonsterile Compounding Room size:	NA	Number of Compounding Pharmacists:	0
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	1
Nonsterile Hazardous Drugs (HD) Compounding Room size:	NA	Total Technicians:	73
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	0
Sterile Compounding Ante Room size:	NA	Of technicians, how many are nationally certified?	54
Sterile Compounding Clean/Buffer Room size:	NA	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	15
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	0
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	NA		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	5000	Total Orders Distributed/day:	0
% Veterinary Prescriptions	1%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	Aurora Pharmacy, Inc. dba Aurora Pharmacy #1143
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	Yes	Livewell App (via Epic system)
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	Yes	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	In patient portal app
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		

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		Observation	Notes
Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Pharmacy delivers to clinic for administration (e.g. Spravato). The pharmacy white bags.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	Yes	Central fill pharmacy
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
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Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	WI BOP Inspection on 4/20/2017
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

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Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC Specialty Pharmacy, ACHC Specialty Pharmacy, URAC- Mail Order Pharmacy
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	The pharmacy maintains records onsite for 3 years and sends records to Iron Mountain for offsite storage for 7 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Both verbal and written prescriptions are kept onsite for three years.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic, faxed, and e-scripts are maintained onsite for three years. Hard copy prescriptions are scanned into pharmacy system (EPIC).
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Dispensing records are maintained the entire retention period.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	The pharmacy has a system to prevent pharmacy records from being deleted. The pharmacy has backup servers.

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Handled by corporate and the PIC/Clinical Pharmacy Manager. The manager reviews state board newsletters and reports weekly to ensure compliance.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	The PIC verifies licensures through the licensing verification portal provided by the state board.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Separate from the other pharmacy, it is centrally monitored by the healthcare system's public safety team.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Handled by corporate. Pharmacy will close and transfer to services to nearest Aurora Pharmacy location.

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Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The patient area is located at the front entrance of the pharmacy, between the secured pharmacy entrance and the patient entrance. The area is locked to prevent patients from entering while counseling is being conducted
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	SensorScientific. See Doc01-GP39_Aurora Specialty Pharmacy_Menomonee Falls_WI
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	The pharmacy has three monitoring systems used to monitor ambient temperature 24/7.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	

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Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
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Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Alerts are sent every 15 minutes, when temperatures are out of range. The pharmacy will move the drugs to a different facility or refrigerator within a 3-hour window during excursions. Notifications are sent to PIC and managers.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	See Doc01-GP39_Aurora Specialty Pharmacy_Menomonee Falls_WI
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	Corflex automation
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

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		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	Handled by corporate.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	Yes	Pharmacy may transfer inventory from other Aurora Pharmacy locations.
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	No	
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes. Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor (For instance. does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Yes	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	Handled by corporate.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Handled by corporate.

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		Observation	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	Handled by corporate.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	external systems, verified by epic
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	CSOS, POA (pharmacists and technicians)
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	CSOS, POA (pharmacists and technicians)
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

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		Observation	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	Aurora Pharmacy #1143 dispenses compounded products.
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Handled by corporate.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	Controlled substance inventory is reconciled daily.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Unknown	
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	N/A	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	N/A	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	Yes	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy pulls expired medication from active stock six months in advance.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	Yes	60 days. See Doc02-GP61_Aurora Specialty Pharmacy_Menomonee Falls_WI
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	Yes	60 days
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
	Prescription Processing If any part of a question is no, enter "No" and explain the observation.		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	The pharmacist enters the patient information via Epic system.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Less than 0.01% dispensed.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Electronic prescriptions, verbal orders, and rarely mail-in DURs are processed.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The pharmacists verify the prescription via the EPIC system and by calling the physician.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The verification is completed via Epic system.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The system identifies both.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Pharmacist responsibility to enter, flag hard holds it. Date day supply
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	Yes	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Epic
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	Yes	Remote workers, 2 pharmacist and 2 technicians housed in IL.

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	Yes	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	Yes	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	Yes	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	N/A	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Pharmacy does not have a toll free number. Pharmacy has 24/7 pharmacist available to answer questions.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Printed and shipped with drugs mailed and central filled for the pharmacies.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Printed and shipped with drugs mailed and central filled for the pharmacies.

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e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	REMS (Sublocade, Spravato, Brixadi). The pharmacy dispense drugs through "clear bagging" process.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how*	Yes	Epic triggers the call, for new and change of therapy. Captured by a third, Enliven health captures the counseling and denied counseling.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	No	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	No	

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Facility Name: Aurora Pharmacy, Inc. dba Aurora Specialty Pharmacy
e-Profile ID: 1420370
Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Quality is completed by Thomy and corporate. The quality team conducts biweekly meetings.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Both hard copy and electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	System-wide training is conducted annually, with a review by the director. Training covers compliance, HIPAA, and compounding, which is administered by the compounding team

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		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Handled by Corporate
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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Inspection Date: 11/18/2024 - 11/19/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Handled by Corporate.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	Origami Safety System, Centralized safety team.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

EXPIRES: 05/31/2026

NO. 9438 - 42

The State of Wisconsin
Department of Safety and Professional Services
PHARMACY EXAMINING BOARD

Hereby certifies that

AURORA SPECIALTY PHARMACY

THOMY SINGH

N93 WI4575 WHITTAKER WAY MENOMONEE FALLS WI

was granted a license to operate a

PHARMACY

in the State of Wisconsin in accordance with Wisconsin Law
on the 1st day of December in the year 2016.
The authority granted herein must be renewed each biennium by the granting authority.
In witness thereof, the State of Wisconsin
Pharmacy Examining Board
has caused this certificate to be issued under
the seal of the Department of Safety and Professional Services

STATE OF WISCONSIN
DEPT. OF SAFETY AND PROFESSIONAL SERVICES

DSPS Secretary

Chairperson

Secretary

This certificate was printed on the 13th day of May in the year 2024

STATE OF WISCONSIN Department of Safety and Professional Services

Electronic Licensure Verification

This real-time Licensure Verification page is electronically certified proof of licensure, as requested, and as it appears in the files of the State Of Wisconsin - DSPS as of Monday, February 10, 2025 9:35:39 AM - Central Standard Time

Printer Friendly

License Information

Name	AURORA SPECIALTY PHARMACY
Credential Type	Pharmacy (in state)
Credential Number	9438-42
Location	MENOMONEE FALLS, WI
Status	credential license is current (active)
Issue Date	12/01/2016
Expiration Date	05/31/2026
Disciplinary Order(s)	No
Licensee	AURORA SPECIALTY PHARMACY

The information above is the only certification information provided by this Department. To expedite the certification process, the above format is the standard format for all professions required by this Department.

Aloysius F. Rohmeyer

Aloysius F. Rohmeyer
Record Custodian
Department of Safety and Professional Services

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA6482943	06-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	CENTRAL FILL PHARMACY	05-02-2022

AURORA SPECIALTY PHARMACY
N93W14575 WHITTAKER WAY
MENOMONEE FALLS, WI 530511652

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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AURORA SPECIALTY PHARMACY
N93W14575 WHITTAKER WAY
MENOMONEE FALLS, WI 530511652

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Form DEA-223 (9/2016)

Licens E (/s/)

Home

Request Support

DSPS Site Guest User

Third Party Document Upload Application Status Lookup LEAP Login

Provider Login Performance Data File a Complaint

Orders and Disciplinary Actions License Lookup

Credential/License Summary for 9438 - 42 As of March 17, 2025 7:05:24 AM

Name : AURORA SPECIALTY PHARMACY

Credential/License Number : 9438 - 42

Professions : Pharmacy (In-State)

Location : MENOMONEE FALLS, Wisconsin - 53051

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2016-12-01

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 9438 - 42

No Orders Found

Relationships for 9438 - 42

Individual

NAME
Thomy X Singh

LICENSE NO 17509 - 40 (/s/licenseView?id=0cE3d00000002xJEAQ)

LOCATION Milwaukee, Wisconsin

TYPE Managing Person

START DATE 2022-11-05

1 - 1 Records: 1
of 1

Organization

No Organization Relationships Found

ATTENTION: The information provided through this public lookup constitutes official certification of licensure information and credential verification for professions regulated by the Wisconsin Department of Safety and Professional Services and its attached boards. If a renewal application including payment is received by the expiration date, the credential holder is eligible to practice while the credential renewal is processed. The credential holder must respond to any requests for information during the renewal process. See Wis. Stat § 227 51(2). Consistent with The Joint Commission and NCQA standards for primary source verification. Send questions or comments to dsps@wisconsin.gov (mailto:dsps@wisconsin.gov)

Contact Information

4822 Madison Yards Way Madison, WI 53705

(608) 266-2112 (tel:+6082662112) (877) 617-1565 (tel:+8776171565)

(https://www.wisconsin.gov/)

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4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☐ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Get Relief RX

Physical Address: 149 Shiloh Road, Ste. 7

City: Billings State: MT Zip: 59106

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (406)201-9403 Toll Free # (NAC 639.708, NRS 639.23286): (888) 534-5687

Fax: (406)643-7160 Contact Email: getreliefrx@gmail.com

Website: NA

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Saeed Sadri

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21925

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Saeed Sadri	NV Pharmacist Registration #: 21925
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Get Relief RX, LLC

Mailing Address: 149 Shiloh Road, Ste. 7

City: Billings State: MT Zip: 59106

Telephone: (281)796-3079 Email: crull@refugecapfund.com

Contact Person Name: Crull Chambless

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/Operator (title) for Get Relief RX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Crull Chambless

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/11/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Crull Chambless hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner/Operator (title) for Get Relief RX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Crull Chambless

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

02/11/25

Date

Board Use Only	Date Received: 2/24/25	Amount: $500-ck 1010

This is an initial application for a nonresident pharmacy permit. Our legal name is Get Relief RX, LLC at 149 Shiloh Road, Suite 7, Billings MT 59106. Phone number is 406-201-9403 and our fax number is (406) 643-7160. Below is the list of owners.

Business Address for Each Owner:
Get Relief Rx
149 Shiloh Rd, Ste 7
Billings, MT 59106

Business Phone for Each Owner:
Ph: 406-201-9403

Owners:

33.3%
Crull Chambless- Partner
[redacted]

33.3%
Bruce Smith- Managing Partner
[redacted]

33.3%
Aubrey Prince- Partner
[redacted]

MONTANA

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE

I, **CHRISTI JACOBSEN**, Secretary of State for the State of Montana, do hereby certify that:

GET RELIEF RX LLC

duly filed its **Articles of Organization for Domestic Limited Liability Company** in this office on **February 7, 2024,** and on that date was authorized to transact business in this state **for a term of perpetual duration.**

Payment is reflected in the records of the Secretary of State for all fees owed to the Secretary of State.

No articles of dissolution have been placed on the record in this office by said limited liability company and the records indicate the limited liability company is in good standing under the laws of the State of Montana.

The Secretary of State cannot certify that tax and penalties owed to this state on record with the Department of Revenue are current. Please contact the Department of Revenue at (406) 444-6900 to obtain information on the tax status.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of the State of Montana, at Helena, the Capital, this 6th day of June, 2024.

Christi Jacobsen
Montana Secretary of State

Certificate Number: 56058423

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Get Relief RX, LLC

Pharmacy/Wholesaler License # (if applicable) PHA-PHR-LIC-103965

Physical Address 149 Shiloh Road, Ste. 7

City Billings State MT Zip 59106

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (406)201-9403 Website NA

Licensing Company Email crull@refugecapfund.com

Section 2: Personal Information

First Crull Middle _____ Last Chambless Type text here

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Billings State MT Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Belhaven College	08/00 - 05/03

Address	City	State	Zip
1500 Peachtree St.	Jackson	MS	39202

Diploma/Degree obtained, if any: Business MBA

School Name	From - To (MM/YY – MM/YY)
Mississippi College	08/1992 - 05/96

Address	City	State	Zip
200 S. Capitol Street	~~Clit~~ Clinton	MS	39056

Diploma/Degree obtained, if any: Business/Marketing BA

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2009 - Present	[redacted]	Billings	MT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Shepherd Holdings			08/2019 - Present
Business Address	**City**	**State**	**Zip**
149 Shiloh Road STE 9	Billings	MT	59106
Phone	**Title**	**Number of Employed Hours**	
281-796-3079	Owner	58,400+	
Description of Duties			
Meets with Investors, runs sales for subsidaries.			

Business Name			From - To (MM/YY – MM/YY)
Get Relief RX			01/24 - Present
Business Address	**City**	**State**	**Zip**
149 Shiloh Road STE 7	Billings	MT	59106
Phone	**Title**	**Number of Employed Hours**	
888-534-5687	Owner	11,000 +	
Description of Duties			
Contact for the Board members, Runs management for the pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Crull Chambless, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CC I am at least 21 years of age;
3. CC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Crull Chambless

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Crull Chambless
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/11/25
Date

Please have this section completed in the presence of a Notary Public.

State of Montana, ss. County of Yellowstone

I, Crull Chambless, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/11/25
Date

Subscribed and Sworn to before me this 11TH day of February.

Notary Public Signature

TAWNI RAE PALIN NOTARIAL SEAL STATE OF MONTANA

NOTARY PUBLIC for the State of Montana
Residing at Billings, Montana
My Commission Expires August 5, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Get Relief RX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 149 Shiloh Road, Ste. 7

City Billings State MT Zip 59106

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (406)201-9403 Website NA

Licensing Company Email getreliefrx@gmail.com

Section 2: Personal Information

First Bruce Middle _____ Last Smith

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Billings State MT Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wheaton College			
Address	**City**	**State**	**Zip**
501 College Ave.	Wheaton	IL	60187
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Northwestern University			
Address	**City**	**State**	**Zip**
633 Clark St.	Evanston	IL	60208
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Shepherd Holdings, LLC	2019 - Present

Business Address	City	State	Zip
149 Shiloh Rd STE 9	Billings	MT	59106

Phone	Title
	Owner

Description of Duties

Managing 28 subsidiary companies

Business Name	From - To (MM/YY – MM/YY)
ClarityORG	2013 - ~~2018~~ 2019

Business Address	City	State	Zip

Phone	Title
	Founder

Description of Duties

Coaching Church Growth 13 churches 2 Non-profits

Business Name	From - To (MM/YY – MM/YY)
Church SolutionS Group	2005 - 2012

Business Address	City	State	Zip

Phone	Title
	Founder / CEO

Description of Duties

multi-discipline church consulting

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bruce Smith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Montana, ss. County of Yellowstone

I, Bruce Smith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/19/25

Date

Subscribed and Sworn to before me this 19th day of February.

Notary Public Signature

TAWNI RAE PALIN NOTARIAL SEAL STATE OF MONTANA

TAWNI RAE PALIN
NOTARY PUBLIC for the
State of Montana
Residing at Billings, Montana
My Commission Expires
(Seal) August 5, 2028

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Get Relief RX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 149 Shiloh Road, Ste. 7

City Billings State MT Zip 59106

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (406)201-9403 Website NA

Licensing Company Email getreliefrx@gmail.com

Section 2: Personal Information

First Crull Middle _____ Last Chambless

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Billings State MT Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Belhaven College		8/2000 - 5/2003	
Address	City	State	Zip
1500 Peachtree Street	Jackson	MS	39202
Diploma/Degree obtained, if any			
Business MBA			

School Name		From - To (MM/YY – MM/YY)	
Mississippi College		8/1992 - 5/1996	
Address	City	State	Zip
200 S. Capitol Street.	Clinton	MS	39056
Diploma/Degree obtained, if any			
Business/Marketing BA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2009 – Present	[redacted]	Billings	MT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Shepherd Holdings, LLC	2019 - Present

Business Address	City	State	Zip
149 Shiloh Road STE 9	Bllg-Billings	MT	59106

Phone	Title
	Owner

Description of Duties: Manging 28 Subsidiary companies

Business Name	From - To (MM/YY – MM/YY)
Harvest Church	10/09 – 06/20

Business Address	City	State	Zip
1235 W. Wick Ln.	Billings	MT	59105

Phone	Title
	COO Executive Pastor

Description of Duties: oversee staff, ministries, and operations of Harvest Church

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Crull Chambless

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/3/24

Date

Please have this section completed in the presence of a Notary Public.

State of Montana, ss. County of Yellowstone

I, Crull Chambless, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/3/24

Date

Subscribed and Sworn to before me this 3 day of December.

Notary Public Signature

TAWNI RAE PALIN NOTARIAL SEAL STATE OF MONTANA

TAWNI RAE PALIN
NOTARY PUBLIC for the
State of Montana
Residing at Billings, Montana
My Commission Expires
August 5, 2028

(Seal)

-cc.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Get Relief RX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 149 Shiloh Road, Ste. 7

City: Billings State: MT Zip: 59106

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (406)201-9403 Website: NA

Licensing Company Email: getreliefrx@gmail.com

Section 2: Personal Information

First: Aubrey Middle: Last: Prince

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Madison State: MS Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LOUISIANA STATE UNIVERSITY		8/73 – 5/79	
Address	**City**	**State**	**Zip**
	BATON ROUGE	LA	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/22 – 12/24	[redacted]	Madison	MS	[redacted]
8/18 – 8/22		Madison	MS	
10/89 – 8/18		Jackson	MS	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: SHEPHERD HOLDINGS			From - To (MM/YY – MM/YY): 2/07 – 12/24
Business Address: 149 Shiloah Rd	City: Billings	State: MT	Zip: 59106
Phone: 601-316-7671	Title: PRES		
Description of Duties: Sales & Admin			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 3: Arrests, Detentions, Litigation, Arbitration	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aubrey Prince

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of MS, ss. County of Rankin

I, Aubrey Prince, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/5/24

Date

Subscribed and Sworn to before me this 5 day of December 2024

Mary S Austin

Notary Public Signature

STATE OF MISSISSIPPI MARY S AUSTIN NOTARY PUBLIC RANKIN COUNTY My commission expires October 17, 2026 Commission number 100456

(Seal)

Montana Department of LABOR & INDUSTRY

Board of Pharmacy

02/04/2025

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY SUITE 206
RENO, NV 89521

I do certify that a standard search of available records of the office of the Montana Board of Pharmacy is considered the primary source and indicates the following:

Licensee Name:	**GET RELIEF RX LLC**		
Mailing Address:	**149 SHILOH RD STE 7** **BILLINGS, MT 59106**		
License Number:	**PHA-PHR-LIC-103965**	**License Type:**	**COMMUNITY PHARMACY**
Original License Date:	**05/14/2024**	**Expiration Date:**	**11/30/2025**
License Status:	**Active**	**Licensure Method:**	**Application**

Endorsement Information:

Endorsement Type	Start Date	End Date
Technician Utilization Plan	03/11/2024	

Actions:

Our records show no adverse information concerning this licensee.

This verification is accurate for all disciplinary actions occurring after July 1, 1996. We cannot guarantee the accuracy of disciplinary actions prior to this date. However, every reasonable effort has been made to provide complete and accurate information. For information about related rules and regulations, go to http://www.pharmacy.mt.gov .

Acting on behalf of the Montana Board of Pharmacy.

Kevin Bragg

Signature

Bureau Chief

Title

Montana Department of Labor & Industry
Employment Standards Division
301 S. Park Avenue
PO Box 200513
Helena, MT 59620
(406) 444-6880
DLIBSDHelp@mt.gov

State of Montana

Business Standards Division

Professional and Occupational Licensing Bureau

Board of Pharmacy

Click here for a disclaimer

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License Information

Licensing Board/Program: Board of Pharmacy

License Type: Community Pharmacy License

License Number: PHA-PHR-LIC-103965

License Status: Active

License Expiration Date: 11/30/2025

License Issued Date: 05/14/2024

License Holder

Business Name: GET RELIEF RX LLC

Name:

City, State Zip: BILLINGS, MT 59106

Facility Information

Address: 140 SHILOH RD STE

Address: 149 SHILOH RD STE 7

City, State Zip: BILLINGS, MT 59106

Relationships

Person In Charge: DENNIS RUDOLPH

Endorsements

With endorsements of:
* *TECHNICIAN UTILIZATION PLAN*

Public Documents

Our records show no public documentation for this licensee.

Discipline

Our records show no adverse information concerning this licensee.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

			Inspection Information
Business e-Profile ID:	1808699		
Legal Business Name:	Get Relief RX, LLC	**Conference Call Date:**	N/A
Doing Business As (DBA):	N/A	**Start Time: 24-hour format (13:00)**	N/A
Address:	149 Shiloh Rd, Ste 7	**End Time: 24-hour format (13:00)**	N/A
City:	Billings	**Onsite Inspection Date(s):**	8/8/2024
State:	Montana	**Start Time(s): 24-hour format (13:00)**	9:07
Zip Code:	59106	**End Time(s): 24-hour format (13:00)**	16:10
Telephone number:	N/A	**Inspector Name(s):**	Nancy Hall, PharmD
Toll free number:	888/534-5687	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	406/643-7160	**Observer Name/Affiliation (if applicable):**	Lindsay Wall/Pharmacy Consultant contracted by the pharmacy.
Website:	www.getreliefrx.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 28.02, 29.00, 37.00, 37.03, 39.01, 43.00, 47.04, 47.06, 47.07, 64.00, 65.00 - 65.03, 66.00, 67.00, 72.00 - 72.03, 83.00, 88.00, 88.03, 89.00, 91.01, 93.00

Nonsterile - 2.0, 2.1, 2.5, 2.6, 3.0 3.3, 8.0, 8.3, 10.0, 10.3, 15.0, 15.4, 15.5, 18.0, 18.2, 18.3, 18.5, 26.0, 26.2, 26.3, 26.5, 27.0, 27.2, 28.0, 28.4, 28.5, 28.10, 29.0, 29.7. 29.9, 29.11, 29.12, 29.13, 29.15, 31.0, 31.1, 45.0, 45.1, 45.3, 49.0, 49.1, 59.0, 59.3, 59.4, 59.5, 59.7, 61.0

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:30	16:30	
Tuesday	8:30	16:30	
Wednesday	8:30	16:30	
Thursday	8:30	16:30	
Friday			X
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Dennis Rudolph	dennis@getreliefrx.com	302356
Nonsterile Designated person(s)	Dennis Rudolph	dennis@getreliefrx.com	302356
Sterile Designated person(s)	N/A		
Hazardous Designated person(s)	N/A		

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Dennis Rudolph	PIC	Y
2	Mayzie Manning	CPhT	Y
3	Lindsay Wall	Consultant RPh	N/A
4	N/A		
5			
6			
7			
8			
9			
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Montana Board of Pharmacy	Get Relief Rx LLC	Pharmacy	PHA-PHR-LIC-103965 Exp: 11/30/2024

Inspector Notes: List states in which Non-Resident licenses are held: AZ, WY. Also shipping into MA - no non-resident license is required. Get Relief RX, LLC, is a new mail-order pharmacy opened in the last 2 months. They dispense only one drug, a CNSP to contain both cetirizine 8 mg and famotidine 22 mg. The pharmacy has three owners who are also affiliated with a Gastro-enterology physician of Jackson MS, and a digital marketing company, Shepherd Holdings, at 149 Shiloh, Suite 9, Billings MT. Shepherd Holdings performs data mining from digital sources seeking people with GI-related issues. They reach out to the person via email or text regarding the GI-related issue, offering to contact them to evaluate their condition via an online questionnaire that is forwarded to the doctor who then prescribes the CNSP capsule with cetirizine 8 mg and famotidine 22 mg, which the pharmacy compounds from commercial tablets, and mails to the patient. The CNSP is dispensed in bottles of 30 capsules to take one capsule at bedtime. Per the PIC, the questionnaire, physician evaluation, prescription information, patient address, and dispensing information, is maintained in a proprietary database, QuickBase. Per the PIC, the physician cannot access all the information on the pharmacy side of the database, and the pharmacy staff cannot access all the information on the physician side of the database. Per the PIC, the physician will only contact and speak to the patient if he has concerns based on the questionnaire answers. It does not appear the pharmacy is involved in any patient billing. There is also a physician in MA who prescribes the CNSP via QuickBase. Refills are processed through the physicians' offices. The pharmacy is seeking an inspection to apply for additional nonresident state licenses, but is not seeking NABP accreditation. The pharmacy is utilizing a consultant, Lindsay Wall, to assist with the set-up of the pharmacy, who was present during the first 3+ hours of the inspection but did not participate in the inspection.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Photo01_GP37.00; Photo02_NS8.3; Photo03_NS18.3; Photo04_NS31.1.	Photos of a trash can with white powder, powder residue in blender, dust on a V1 mixer, and unlabeled inventory stock.
Doc01_GP88.00; Doc02_NS28.0; Doc03_NS29.0.	Documents of an ARL COA for a CNSP, a MFR example (2 pages), and the observed CNSP CR.

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy	X	Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations	X (capsules)	Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	1400 total (800 in the general pharmacy/600 in the washing room and another office supply room)	Total Pharmacists:	1
Nonsterile Compounding Room size:	64	Number of Compounding Pharmacists:	1
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	0	Total Technicians:	1
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	1
Sterile Compounding Ante Room size:	0	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	0
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	1:1 (4:1 allowed in MT)
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	0		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:	0-9	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	100%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)	9	0	July 2024
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)	5	0	July 2024
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)	12	0	July 2024

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)	2	0	July 2024
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	34 hours/week. The pharmacy is open Monday-Thursday.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	The www.GetReliefRx.com website links to Dr. Reed Hogan III for a review of the health questionnaire to determine if he will prescribe the CNSP to the patient.
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	The patient can request a refill through the website which notifies Dr Reed Hogan III or Dr Chinyere Ezeh (based on the original prescription), where the MD office will approve the refill which generates the refill to the pharmacy's QuickBase queue dispensing list.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Mayzie Manning CPhT.

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Facility Name: Get Relief RX, LLC
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		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Get Relief RX, LLC

e-Profile ID: 1808699

Inspection Date: 8/8/2024

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	No	Closed door pharmacy. Licenses are maintained in a binder in the pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	N/A	The pharmacy has not been inspected by the MT BOP or FDA.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	N/A	
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

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Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	The pharmacy does not have a federal DEA license.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	No	Records are maintained electronically and backed up to an offsite server for at least 10 years. The location of the offsite server is not known by the PIC.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	N/A	The pharmacy is not receiving any written or verbal prescriptions.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Unknown	The pharmacy is not receiving electronic prescriptions but receives prescription-related data from the prescriber through the QuickBase patient database. QuickBase is part of the backed-up information.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	No	Records are maintained electronically in QuickBase and backed up to an offsite server for at least 10 years. The pharmacy does not receives copies of the original prescription but receives limited prescription-related data via the QuickBase queue.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Per the PIC, QuickBase does not allow record deletion.

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Facility Name: Get Relief RX, LLC

e-Profile ID: 1808699

Inspection Date: 8/8/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	Records maintained on the electronic database are restricted by password protected firewalls.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Unknown	This is not clearly stated in the P&P. It is the PIC's responsibility to keep up with laws and regulations in MT. They have a consultant who will be keeping up with new laws and regulations for other states, and will notify the PIC and owners.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Licenses are current, documented with active licenses. The PIC is developing a calendar on Google to give a month advanced notice of upcoming expiring dates for all employees.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Licenses in MT are renewed annually and will be reviewed with each renewal by having the employee bring in the renewed license for placement in the binder.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	Currently using 1:1 ratio. MT allows a 4:1 ratio. Currently the maximum staff is 2.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The pharmacy has an in-house system with contact alarms on the 2 outside doors and 1 internal door to the general building hallway. There is no audible alarm. If the contact is triggered by opening of the door, it sends a text to the PIC's cell phone. The PIC can look at the 3 internal cameras at any time. There is no activation/deactivation of the security system.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	No controlled substances in the pharmacy.

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Facility Name: Get Relief RX, LLC

e-Profile ID: 1808699

Inspection Date: 8/8/2024

		Observation	Notes
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The medications would be moved to the lockable owner's suite next door (Shepherd's Holding in Suite 9). The PIC would be present until the building could be secured/boarded up. The landlord would be notified for repairs.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Unknown	The pharmacy has adequate space for the prescription volume and is neat and orderly. There is a white dust clinging to the sides of the trash can in the sink room that appears to be possible CNSP waste, and there is white dust inside the lid of the tablet blender. Per the PIC he may have disposed of a batch of CNSP waste in the trash can. Other parts of the pharmacy are clean. Photo01_GP37.00.
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	Unknown	They report they do not destroy any drugs on site, however there is an unknown white powder in the trash can in the room where compounded drugs containers are washed. Per the PIC he may have disposed of a batch of CNSP waste in the trash can.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	N/A	This is yet to be determined.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	N/A	
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	This is a closed door pharmacy. Patients can call the pharmacy from the toll-free 888 number on the Rx bottle which call goes to the receptionist at the Shepherd's Holding office, who would let the pharmacy know the patient wants a call back.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Get Relief RX, LLC

e-Profile ID: 1808699

Inspection Date: 8/8/2024

		Observation	Notes
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The pharmacy has HVAC systems to maintain temperature with a thermostat inside the general pharmacy area. The temperature and RH are recorded morning and afternoon for each day the pharmacy is open, from a reading of a small ThermPro digital thermometer. There is no tracking of the temperature/RH over the weekends or days the pharmacy is closed. 72°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process.*	No	There appears to be a min/max setting on the ThermPro thermometer that is not utilized or recorded.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	The PIC would contact the manufacturer for guidance to determine if the involved temperatures impact drug integrity.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	N/A	There are no refrigerated or frozen drugs.
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	N/A	
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	No	

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		Observation	Notes
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Pharmacy staff would call the landlord for urgent repairs. The PIC also has contact information for the HVAC installer who could be contacted for repairs.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	The PIC would contact the manufacturer for guidance to determine if the involved temperatures impact drug integrity.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The pharmacy requires the source to be licensed in their location state, in MT, and to have a NABP Drug Distributor Accreditation.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	They are purchasing from a wholesale distributor.
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Anda
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Unknown	It is unknown if it is a requirement to purchase from a wholesale distributor who purchases directly from a manufacturer, but that is what they have done thus far with their purchases from Anda.

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		Observation	Notes
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	They rely on Anda to track licensing of the Anda sources. The pharmacy keeps the packing slip and invoice for their orders.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	They rely on Anda to track licensing of the Anda sources. The pharmacy keeps the packing slip and invoice for their orders.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	They have a process in their P&P they describe as contacting the wholesale distributor for further information and to explain their concerns.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	To date they kept the shipment invoice which contains the transaction data and a direct purchase statement. They will be contacting the source, Anda, to provide the detailed DSCSA transaction data.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	No	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	

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		Observation	Notes
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	N/A	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc)*	Yes	The PIC performs a monthly inventory for quantity and expiration date.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	They would notify the BOP. No instances to date.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	

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Inspection Date: 8/8/2024

		Observation	Notes
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	N/A	
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	N/A	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	These would be placed in the marked quarantine bin. Outdates checked monthly and pulled 6 months prior to expiration.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	For those items observed during the inspection.
60.02	How often is active-stock examined for drugs past the expiration date?		Monthly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	

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		Observation	Notes
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	N/A	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	Closed door pharmacy. All their drugs are shipped via USPS to patients.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	No	The pharmacy does not maintain a patient profile for their dispensing. Patient information in QuickBase is limited to the patient name and address.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Unknown	Prescriptions are only from two physicians, that are entered into QuickBase. Per the PIC prescriptions are written for patients based on an online questionnaire and may not reflect direct physician-patient discussion.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	No	

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		Observation	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	No	The pharmacy relies on the prescribing physician to ensure the patient is appropriate to receive the drug. It appears the patients may receive the drugs based on an online questionnaire and without a prescriber-patient discussion or interaction.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	No	They do not receive complete prescriptions but receive prescription-related details in the dispensing queue per the closed system QuickBase with information linked to the prescriber.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	No	They rely on the prescriber to perform this service.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	No	They rely on the prescriber to perform this service. They report they are adding a system to QuickBase where they will be able to see other drugs the patient may take and patient allergies.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	N/A	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	N/A	

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		Observation	Notes
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	The PIC has an electronic subscription to Epocrates available on his cellphone.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	N/A	
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	N/A	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	N/A	
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	N/A	
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	The PIC looks at the QuickBase computer screen for the patient name and address to compare to the label, if that's accurate, he then looks at the capsules in the bottle to confirm they are intact, then the PIC prints the shipping label and ensures it matches the Rx label. The RPh initials are entered into QuickBase at the time of printing the shipping label, which indicates the RPh has verified the prescription.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	They appear to contain expected information.

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		Observation	Notes
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	QuickBase. The system has a separate sign-on and passwords for the individual user.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Inhouse shredder.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	Using bubble pack envelopes with first class USPS mail.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	Yes	Patient information is entered by the prescribers, who are not pharmacy employees.
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	No	Patient information is entered by the prescribers, who are not pharmacy employees.
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	Yes	The prescribers are in MS and MA.
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	No	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	This is a closed-door pharmacy.
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	

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		Observation	Notes
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	The prescription vial and the pharmacy/general compounded drug information sheet that accompanies shipments, includes the pharmacy's toll-free phone number. Patients can call the 888 number and reach the Shepherd's Holding receptionist next door, who will forward the call to the PICs personal cell phone number or send him a text message to return the call. After hours, the caller can leave a message to be returned the next day the pharmacy is open. There is no pro-active phone calls for patient counseling.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	None of this type of dispensing.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	None of this type of dispensing.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	No	The pharmacy asked the company owners to add a 'notes' section in QuickBase where the pharmacist can enter patient-specific information.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	A patient can leave a message and have the call returned during normal pharmacy business hours.
85.00	Are processes in place to handle a drug recall?	Yes	They would be notified by their wholesale distributor.
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	

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		Observation	Notes
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The PIC.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Hard copy.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	The information is included on the QRE Report Form and the Rx Incident Report Form, which are in a binder separate from the P&Ps. It is unclear which form is used for a detected issue.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Get Relief RX, LLC

e-Profile ID: 1808699

Inspection Date: 8/8/2024

		Observation	Notes
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	No	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	No	Per the PIC, they would initiate documentation and an investigation as soon as possible and use the Rx incident report form. No forms to review with information below based on the blank forms. The pharmacy had potency testing performed by ARL on a CNSP batch which was below the intended range of 90%-110%, however there was no QRE form filled out to reflect follow-up actions or an investigation. Doc01_GP88.00.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	There are spaces to describe the incident.
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	There are spaces to describe the incident.
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	No	There is a space to describe anything special or unusual about the day the QRE occurred.
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	

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		Observation	Notes
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	No	Per the PIC, he would perform root cause analysis with each incident. They have an Annual Quality Program Review form they anticipate using quarterly. The pharmacy had potency testing performed on a CNSP batch which was below the intended range of 90%-110%, however there was no QRE form filled out to reflect actions or an investigation.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	Per process.
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	They plan to have quarterly quality staff meetings. None held to date due to recent pharmacy opening.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	N/A	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	N/A	

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		Observation	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	If the QRE resulted in a recall, it would be reported to the BOP. None to date.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	No	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	They plan a quarterly review of quality issues, or with any specific issues. No audits to date.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	They report they have had no patient complaints.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes	Per the provided self-assessment.	11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		Designation: SOP 3.00 Cleaning: SOP 3.02	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		SOP 2.00 F 2.00.01	2, 11

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
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		Observation	Inspector Notes	USP Reference(s)
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		SOP 2.02	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		SOP 7.00 Selection SOP 7.01 Evaluation	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		SOP 3.01	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		SOP 4.00 "The Assessment is F 4.00.01 Equipment Need is Assessment."	6.1, 11

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		Observation	Inspector Notes	USP Reference(s)
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		SOP 3.03	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		SOP 1.01	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		SOP 6.07 Release Inspections	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		SOP 1.04 Personnel SOP 1.05 DP SOP 6.04 QA Program	11, 12 USP <1163>

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Facility Name: Get Relief RX, LLC
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		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		SOP 6.02 Complaint Handling	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		SOP 7.00	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		SOP 5.02	11, 13.2

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		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		SOP 6.06	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Unknown	The pharmacy had copies of the prior USP 795 and did not update to the new USP 795 until made aware by the inspector.	1.1.4

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		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Unknown	It is unclear if the PIC has the training and experience as there were no training records to review.	1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes	This is a new pharmacy that opened in May/June of 2024 and began compounding and dispensing in June 2024. The SOPs are newly developed with input of a consultant.	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Unknown	It appears there was no potency testing or other evaluation performed on the CNSP to assess their MFR prior to initial dispensing to patients.	1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Unknown	The pharmacy had copies of the prior USP 795 and did not update to the new USP 795 until made aware by the inspector.	1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
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		Observation	Inspector Notes	USP Reference(s)
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Unknown	This is a new pharmacy and the training program is newly initiated without clear documentation of requirements. There are only two staff and training records are only present for PT Mayzie Manning.	2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No	The PIC has limited compounding experience in the past. Per the PIC, he reached out to Richie's pharmacy in Houston and a pharmacy owned by Reed Hogan Sr, for some guidance. PT Mayzie Manning has approximately one year's experience with compounding from another pharmacy and repeated some USP CEs for nonsterile and sterile compounding. The consultant Lindsay Wall comes as needed and is available daily by telephone.	2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No	The PIC performs the in-process checks, however he does not have documented training available to review during the inspection.	2, 14

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
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Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	No	The PIC does not have documented training available to review during the inspection.	2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	No		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

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		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes	Hard copies in a binder.	3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes	Washable lab coat, disposable shoe covers, N95 masks, gloves, bouffants.	3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes	Lab coats are washed when visibly soiled or at least once monthly in a washer/dryer in an adjacent space. They anticipate ordering disposable gowns to use for compounding.	3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes	A segregated compounding space with a loose sliding door that can be closed to limit noise. The automatic capsule machine is along one wall in the general pharmacy space outside the segregated compounding room.	4.1
8.2	The compounding area is well lit.	Yes		4.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
8.3	The compounding area is clean and sanitary.	No	There is some residual powder in the lid of the tablet crushing blender and in a trash can in the sink/washing room. Photo01_GP37.00, Photo02_NS8.3.	4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		4.2

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Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes	Temperatures are on written logs recorded morning and afternoon on days the pharmacy is open. The log for August is not dated but per the PIC, the month and year will be written on the paper at the end of the month.	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	No	Temperature readings taken from a ThermPro digital thermometer located in one corner of the general pharmacy space. This thermometer is not calibrated.	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		72°F	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3

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		Observation	Inspector Notes	USP Reference(s)
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	No	Rinsed with tap water.	4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		They clean shelves and equipment with 70% IPA as listed on the cleaning log. Floors are cleaned with Zep, not listed on the cleaning log.	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	No	The cleaning log indicates countertops are cleaned every day of the month, however they are actually cleaned only days the pharmacy is open (M-Th).	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	N/A	Their compounding is limited to the same CNSP.	5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	No	Floors cleaned once a week using Zep (as labeled) but the Zep is not listed on the cleaning log.	5 Table 1

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		Observation	Inspector Notes	USP Reference(s)
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	No	Walls and ceilings were cleaned when the pharmacy opened approximately 2 months ago, but no plan for recleaning.	5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes	Cleaned once a week with 70% IPA.	5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	No	No PEC in use.	6.1

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		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	No		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	No	Per the PIC this was not performed nor documented. They crush commercially manufactured tablets in a room with a ceiling exhaust fan that vents outdoors. The crushed powder is also handled in the capsule machine area in the general pharmacy area.	6.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	No	There was visible powder inside the lid of the blender used to crush tablets used in compounding. The V1 mixer had dust on the surface which they said they do not clean between compounding batches. Photo02_NS8.3, Photo03_NS18.3.	6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Unknown	Their scale is calibrated with a weight, weekly, and prior to compounding. The scale is located on a rolling table (wheels locked) that vibrates a lot when the RO-tap sieve is shaking. It is unknown if the vibrations impact the scale.	6.1

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		Observation	Inspector Notes	USP Reference(s)
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	No	Compounding is with commercial OTC and Rx tablets.	6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	N/A		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	N/A		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	N/A		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	N/A		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	N/A		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		They are not utilizing water in compounding.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	N/A	They are utilizing Loxasperse from PCCA for which they state they do not receive a COA.	6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A	They are not handling components without a vendor expiration date.	6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4

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24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	No		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5

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26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	No		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	No	Per the PIC these are ordered and awaiting delivery.	6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes	There is a process.	6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Unknown	It appears there is white powdery waste on the sides of the regular trash can in the washing room. Photo01_GP37.00.	1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Unknown		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Unknown	The MFR does not reflect the date of a change in formulation as verbally described by the PIC during the inspection, to reflect updated active drug amount after potency testing identified contents at 81%-84% of expected.	7.1

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27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	No	Doc02_NS28.0.	7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	No	Use of the blender to crush tablets was verbally described for preparation of 300 capsules but not described on the MFR. The amount of time for use of the RO-Tap sieve is not listed on the MFR. Use of the automatic BlateCo capsuling machine is not described on the MFR. The current machine is not being used and a new machine is on order.	7.1
28.5	MFR has a physical description of the final CNSP.	No	#1 orange capsules are listed but the MFR does not include a description of the capsule contents or the lot or expiration date of capsules.	7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes	Stated: Per USP 795.	7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes	Listed on the formulation sheet.	7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Unknown	QC results are not clearly documented.	7.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	No	Doc03_NS29.0.	7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes	The pharmacist listed at the top of the CR is the responsible person to verify the final CNSP.	7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	No	The name, vendor, lot number, and expiration date of the capsules is not listed.	7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes	The weight of components is included.	7.2, 14
29.9	The CR identifies the total quantity compounded.	No		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Unknown	It appears there are CR for prior batches which have unclear total quantity compounded.	7.2, 14
29.12	The CR has a physical description of the final CNSP.	No	#1 orange capsules are listed but the MFR does not include a description of the capsule contents.	7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	No	Per their process, they weigh 1-2 single capsules of a batch of 30-300 capsules as part of their quality control. However the CR may not include the weight of the 1-2 capsules.	7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	No	Due to missing information as described in the above cells of this section.	7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes	Capsules information is not listed.	7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	The pharmacist double checks each weight on the scale.	2, 7.2, 8

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		Observation	Inspector Notes	USP Reference(s)
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	No	Bottles of CNSP capsules, prepared in batches for anticipation of prescriptions, are not labeled. Photo04_NS31.1.	9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes	A BUD is listed, and also the label includes a 'manufacturing' date.	9
31.7	The label on the immediate container includes the dosage form.	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes	This is also included on the compound information sheet sent with the shipments.	9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	N/A		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A	The pharmacy does not establish BUDs that exceed Table 4.	10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A. If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study. If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	No		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	No	The pharmacy dispensed CNSPs from a batch found to be below intended potency of 90%-110% but no action or QA process was documented. Per the PIC he recalculated the amount of commercial tablets to use in the compounding MFR. Per the PIC there were capsules from a batch prepared with the updated MFR sent to ARL for potency testing, however the results are not yet returned to the pharmacy. Doc01_GP88.00.	12

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		Observation	Inspector Notes	USP Reference(s)
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	No	It appears there was no potency testing performed on the CNSP, or other evaluation, to assess their MFR prior to initial dispensing to patients.	12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	No complaints, to date.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes	Per process. There is no documented quality assessment of the subpotent CNSP report from ARL.	12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2

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47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes	Per process, none to date.	12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes	Per process, none to date.	12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes	Per process, none to date.	12.2
47.4	Complaints are fully investigated.	Yes	Per process, none to date.	12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes	Per process, none to date.	12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes	Per process, none to date.	12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Get Relief RX, LLC
e-Profile ID: 1808699
Inspection Date: 8/8/2024

		Observation	Inspector Notes	USP Reference(s)
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Unknown	Per process, none to date.	12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Unknown	It is unclear when a subpotent CNSP is recalled.	12.1
49.2	The pharmacy documents the implementation of the recall.	Yes	Per process, none to date.	12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes	Per process, none to date.	1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes	Per process, none to date.	12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes	Per process, none to date.	12.1

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		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes	Observed compounding performed by PIC Rudolph and PT Manning.	
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes	Per process.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1

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		Observation	Inspector Notes	USP Reference(s)
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	No		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Cetirizine 8 mg/famotidine 22 mg CNSP capsule. Batch of 30 capsules. This was a demonstration compounding and was not intended for dispensing to patients. Doc03.NS29.0.	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2

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		Observation	Inspector Notes	USP Reference(s)
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3

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		Observation	Inspector Notes	USP Reference(s)
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes	The PIC weighed one capsule from batch of 30 capsules to compare to expected weight.	7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	No	There was just the observed CNSP available in the pharmacy to observe visual inspection by the pharmacist.	8, 8.1, 9

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		Observation	Inspector Notes	USP Reference(s)
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	No	The pharmacy does not get a copy of the prescription for comparison purposes.	8, 8.1, 9
59.4	CNSP label was verified against the MFR.	No	Batched CNSP are not labeled when placed in inventory. They are labeled during dispensing.	8, 8.1, 9
59.5	CNSP label was verified against the CR.	No	Batched CNSP are not labeled when placed in inventory. They are labeled during dispensing.	8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1

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		Observation	Inspector Notes	USP Reference(s)
59.7	All checks and inspection that are performed are properly documented.	No	Pharmacist checks are not specifically documented on the CR other than the pharmacist's initials at the top of the CR.	8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	The capsules prepared in advance were not labeled but placed on a post-it note with an apparent batch number. Photo04_NS31.1.	12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	No	The pharmacy does not clean their floors each day of compounding. The top of the V1 mixer was cleaned prior to compounding.	5

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		Observation	Inspector Notes	USP Reference(s)
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	N/A	The pharmacy is currently compounding only one CNSP type with the same components.	5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes	The inside lid of the blender used during some compounding had residual powder. This blender was not used during the observed compounding during the inspection.	6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**PT**	**RPh**	**N/A**	**N/A**	**N/A**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Missing	Yes				Being formalized
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Missing				
1.3	The training record for hand hygiene is complete.	Yes	Yes				
1.4	The training record for garbing is complete.	Yes	Missing				
1.5	The training record for cleaning and sanitizing is complete.	Yes	Missing				
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Missing				

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	Employee Title	PT	RPh	N/A	N/A	N/A	Notes
1.7	The training record for measuring and mixing is complete.	Yes	Missing				
1.8	The training record for proper use of equipment is complete.	Missing	Missing				Specific equipment training is pending.
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Missing				
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	N/A	Missing				
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Missing				
1.12	The training record for spill management is complete.	Missing	Missing				Within the SOPs. Review of SOPs not clearly documented.
2.0	The annual competency assessment was evaluated and documented on the following topics:						This is a new pharmacy and all training is initial.
2.1	Compounding personnel are re-trained on facility SOPs.	N/A	N/A				
2.2	Compounding personnel are re-trained on USP <795> standards.	N/A	N/A				
2.3	The annual competency assessment for hand hygiene is complete.	N/A	N/A				
2.4	The annual competency assessment for garbing is complete.	N/A	N/A				

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	Employee Title	PT	RPh	N/A	N/A	N/A	Notes
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A	N/A				
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	N/A	N/A				
2.7	The annual competency assessment for measuring and mixing is complete.	N/A	N/A				
2.8	The annual competency assessment for proper use of equipment is complete.	N/A	N/A				
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A	N/A				
2.10	The annual competency assessment for interpreting a COA is complete.	N/A	N/A				
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A	N/A				
2.12	The annual competency assessment for spill management is complete.	N/A	N/A				
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Missing	Missing				The nonsterile compounding is performed with both the PIC and PT working together on the compounding.

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

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Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

Pharmacy Name: Get Relief Rx, LLC

Pharmacy Address: 149 Shiloh Rd, Ste 7, Billings, MT 59106

NABP Business e-Profile ID: 1808699

VPP Inspection Date(s): 8/8/24

Sharing Acknowledgment: Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Page No.	VPP Item No.		Facility Response/Corrective Action/Comments	Estimated Date of Action Taken	Attachment (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	14	28.02	entire retention period? Describe how they are kept (electronically or printed and kept in hard copy). The pharmacy is not receiving electronic prescriptions but receives prescription-related data from the prescriber	Get Relief Rx has built its own proprietary PMS and is in the process of integrating with SureScripts and applying for an NCPDP number to receive electronic prescriptions.	01/01/25	N	
Updates/New SOPs or P&Ps	15	29.00	the most stringent laws/regulations are followed? Describe system details. This is not clearly stated in the P&P. It is the PIC's responsibility to keep up with laws and regulations in MT. They have a consultant who will	Our SOPs have been revised to reflect this language.	8/28/24	Y	(Page 1) SOP 1.00 Document Control and SOP Maintenance
Photos	16	37.00	is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo. The pharmacy	The pharmacy's waste disposal procedures have been changed and implemented.	09/03/24	Y	(Page 7) Pic- Waste Tote (Page 8) SOP 7.03 Waste Disposal
Clarification or Further Explanation	16	37.03	if the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? View destruction logs. Mark NA if no destruction on site. They report they	The Stericycle account is currently being set up so that pickups of pharmaceutical waste will occur at least twice annually.	09/13/24	N	
Clarification or Further Explanation	17	39.01	is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. If yes, describe the process. There	twice daily on the days that the pharmacy is open. Additionally, the pharmacy will activate the min/max setting on the ThermPro and	09/09/24	N	
Updates/New SOPs or P&Ps	17	43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? Describe process. No	Our SOPs have been revised to reflect this language.	08/28/24	Y	(Page 16) SOP 3.04 Emergencies and Disasters
Updates/New SOPs or P&Ps	18	47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? If yes, how is this verified? It is unknown if it is a requirement to purchase from a wholesale	that include purchasing only from either the manufacturer directly or from an NABP DDA wholesale distributor.	08/28/24	Y	(Page 20) SOPG 3.009 Vendor Authentication
Updates/New SOPs or P&Ps	19	47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? If yes, describe the process. They rely on Anda to track licensing of the Anda sources. The pharmacy keeps	that include obtaining appropriate licensure, registration, and accreditation certificates from suppliers as well as maintaining	12/01/24	Y	(Page 20) SOPG 3.009 Vendor Authentication
Updates/New SOPs or P&Ps	19	47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? If yes, describe the process. They rely on Anda to track licensing of the Anda	that include checking the FDA WDD/3PL Reporting Database to ensure that the supplier is current on their FDA reporting	08/28/24	Y	(Page 20) SOPG 3.009 Vendor Authentication
Clarification or Further Explanation	22	64.00	Patient Profile: Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? Indicate	date of birth, allergies, medical conditions, diagnoses, and prescription fill history	09/04/24	N	
Clarification or Further Explanation	22	65.00	who enters patient profile data into the computer system and how often. Prescription: Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? Staff is familiar with	pharmacy prescriptions. If another prescriber were to send prescriptions to the pharmacy then the staff has been trained on	09/04/24	N	
Updates/New SOPs or P&Ps	22	65.01	detecting fraud in hard copy, faxed, verbal, and electronic prescriptions. Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? Describe the steps and reporting process. No	The staff has been trained on handling and reporting fraudulent prescriptions.	08/28/24	Y	(Page 22) SOPG 1.307 Fraudulent Prescription Reporting
Updates/New SOPs or P&Ps	23	65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber patient/client	The pharmacy has procedures on handling telemedicine prescriptions and the staff has been trained.	09/05/24	Y	(Page 24) SOP 1.07 Telemedicine Prescriptions
Clarification or Further Explanation	23	65.03	Does the pharmacy have electronic prescription capability? Indicate whether it is for non-controlled substances, controlled substances, or both. They do not receive complete prescriptions but receive prescription	Get Relief Rx has built its own proprietary PMS and is in the process of integrating with SureScripts and applying for an NCPDP number to receive electronic prescriptions	01/01/25	N	
Clarification or Further Explanation	23	66.00	Accuracy: Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? Indicate how and by whom. They rely on the prescriber to perform this	The patient enters their own information when setting up an account on the website.	8/28/24	N	
Clarification or Further Explanation	23	67.00	DUR: Does staff conduct prospective DUR prior to the dispensing of a medication or product? Describe at what point in the process does the DUR take place? They rely on the prescriber to perform this service. They	The pharmacy has added a DUR component to its proprietary PMS.	09/05/24	N	
Clarification or Further Explanation	25	72.00	Off-Site Processes: Are any portions of the prescription processing (in the questions below) performed at a different location? Note: Please ask each question below to verify. Patient information is entered by the	The patient enters their own information when setting up an account on the website.	8/28/24	N	
Other	25	72.01	If yes, is the other location under common ownership? If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.	n/a	08/28/24	N	
Other	25	72.02	If yes, is that location in a different state than this facility? If so, explain: The prescribers are in MS and MA.	n/a	08/28/24	N	
Other	25	72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing? No	n/a	08/28/24	N	
Clarification or Further Explanation	27	83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? Describe how. The pharmacy asked the company owners to add a 'notes' section in QuickBase where the	Closed-door Get Relief Rx provides an insert with all shipments with information on how to reach the pharmacy/pharmacist.	08/28/24	N	
Clarification or Further Explanation	29	88.00	Documentation of QREs starts as soon as possible, but no more than three days, after determining their occurrence. Indicate if	Moving forward, all quality-related events will be documented on this QRE form.	08/28/24	Y	(Page 29) Completed QRE Form
Clarification or Further Explanation	29	88.03	documentation/forms are hard copy or electronic. Per the PIC, they Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty,	A QRE form has been completed regarding the potency testing. Moving forward, all quality-related events will be documented on this QRE form.	08/28/24	Y	(Page 29) Completed QRE Form
Clarification or Further Explanation	30	89.00	prescription volume that day, equipment failure, or other factors affecting QRE data collected is analyzed to assess causes and any contributing factors (root cause). Indicate who performs the analysis and frequency	A QRE form has been completed regarding the potency testing. Moving forward, all quality-related events will be documented on this QRE form.	08/28/24	Y	(Page 29) Completed QRE Form
Updates/New SOPs or P&Ps	31	91.01	(with each event, weekly, monthly, quarterly, etc). Per the PIC, he would Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc? No	Adverse events are reviewed on a case-by-case basis and reported to the appropriate entities according to the pharmacy's policy.	08/28/24	Y	(Page 31) SOP 6.02 Complaint Handling V1.1

Clarification or Further Explanation	31	93.00	Consumer Surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each	Consumer surveys are being implemented and will be distributed to patients between the second and third refills.	09/03/24	N	
Clarification or Further Explanation	36	2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? Inspector note: Per USP, "The compounding facility must designate one or more individuals to be	The pharmacist-in-charge now has a copy of the new USP Chapter 795. He has reviewed the changes and is aware.	8/28/24	N	
Clarification or Further Explanation	37	2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them. It is unclear if the PIC has the training and experience as there	The pharmacist in charge has completed continuing education hours that are relevant to nonsterile compounding.	08/28/24	Y	(Page 35) Dennis Training
Clarification or Further Explanation	37	2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed. It appears there was no potency testing or other	[illegible] for its one and only MFR. Moving forward, the pharmacy will have potency testing performed prior to any new MFR being dispensed.	08/28/24	N	
Clarification or Further Explanation	37	2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified. The pharmacy had copies of the prior USP 795 and did not	The pharmacist-in-charge now has a copy of the new USP Chapter 795. He has reviewed the changes and is aware.	8/28/24	N	
Clarification or Further Explanation	38	3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? Inspector note: Per USP, "Training and competency of personnel must be documented." Inspector is to	The pharmacist in charge has completed continuing education hours that are relevant to nonsterile compounding.	08/28/24	Y	(Page 35) Dennis Training
Clarification or Further Explanation	39	3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. Inspector note: Per USP, "Other personnel,	The pharmacist in charge has completed continuing education hours that are relevant to nonsterile compounding.	08/28/24	Y	(Page 35) Dennis Training
Photos	41	8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? If no, go to compliance statements.	The pharmacy's waste disposal procedures have been changed and implemented.	09/03/24	Y	(Page 7) Pic- Waste Tote
Updates/New SOPs or P&Ps	42	8.3	The compounding area is clean and sanitary. There is some residual powder in the lid of the tablet crushing blender and in a trash can in the sink/washing room.	The pharmacy has implemented new cleaning instructions and equipment will be cleaned after EACH use.	08/28/24	Y	[illegible] (Page 40) SOP 3.02 Cleaning and Maintenance of the Nonsterile Compounding Area v1.1
Other	42	10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? If no, go to compliance statements.	See below	08/28/24	N	
Clarification or Further Explanation	43	10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for	The ThermPro thermometer will be replaced annually.	08/28/24	N	
Updates/New SOPs or P&Ps	45	15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? Review	The SOP and the cleaning log have been changed to reflect that the pharmacy cleans daily on days that the pharmacy is open.	08/28/24	Y	[illegible] (Page 40) SOP 3.02 Cleaning and Maintenance of the Nonsterile Compounding Area v1.1
Updates/New SOPs or P&Ps	45	15.4	Floors are cleaned and sanitized daily on days when compounding occurs. Floors cleaned once a week using Zep (as labeled) but the Zep is not listed on the cleaning log.	The cleaning log has been changed to reflect the cleaning products used.	08/28/24	Y	[illegible] (Page 40) SOP 3.02 Cleaning and Maintenance of the Nonsterile Compounding Area v1.1
Updates/New SOPs or P&Ps	46	15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector	The pharmacy staff has been trained to clean areas if they are visibly soiled even if the area is in between cleaning schedules.	08/28/24	Y	[illegible] (Page 40) SOP 3.02 Cleaning and Maintenance of the Nonsterile Compounding Area v1.1
Other	47	18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive,	See below	09/16/24	N	
Updates/New SOPs or P&Ps	47	18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. Inspector note: Per USP, "components that	The pharmacist in charge will perform a risk assessment to determine any additional pharmacy needs.	09/16/24	Y	(Page 45) SOPF 4.00.01 Equipment Need Assessment
Updates/New SOPs or P&Ps	48	18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. Inspector note: Per USP <795>, "After compounding, the	[illegible] pharmacy cleans between each batch on days that the pharmacy compounds.	08/28/24	Y	[illegible] (Page 40) SOP 3.02 Cleaning and Maintenance of the Nonsterile Compounding Area v1.1
Photos	48	18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). If the pharmacy does	The scale has been moved to a different location so as not to be affected by any vibrations or heat source.	08/28/24	Y	(Page 47) CMP Room 2
Updates/New SOPs or P&Ps	52	26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? If no, go to compliance statements. No	[illegible] management, and disposal information program in compliance with USP <795> standards.	08/28/24	Y	(Page 48) SOP 3.03 Spill Management
Updates/New SOPs or P&Ps	53	26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill. No	Forms have been updated to include spill management competency.	08/28/24	Y	(Page 54) SOPF 3.03.03 Spill Management Competency
Photos	53	26.3	The pharmacy has a readily accessible spill kit in the compounding area. Per the PIC these are ordered and awaiting delivery.	The spill kit is now readily accesible in the compounding area.	08/29/24	Y	(Page 56) Spill Kit Amazon Order
Updates/New SOPs or P&Ps	53	26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction. It appears there is white powdery waste on the sides of the regular trash can in the washing	The pharmacy's waste disposal procedures have been changed and implemented.	08/28/24	Y	(Page 8) SOP 7.03 Waste Disposal
Photos	53	27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared. If	Yes, an MFR has been created for each unique formulation in compliance with USP <795> standards.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	53	27.2	Any changes or alterations to the MFR are approved and documented. The MFR does not reflect the date of a change in formulation as verbally described by the PIC during the inspection, to	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	54	28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment. No	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	55	28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. Inspector note: Per USP, the MFR will also include, "Other information	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	55	28.5	MFR has a physical description of the final CNSP. #1 orange capsules are listed but the MFR does not include a description of the capsule contents or the lot or expiration date of capsules.	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	55	28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results. QC results are not clearly documented.	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	56	29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or	The CR components are on the MFR.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	56	29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component. The name, vendor, lot number, and expiration date of the capsules is not listed.	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	56	29.9	The CR identifies the total quantity compounded. No	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924

Photos	57	29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API. It appears there are CR for prior batches which have unclear total	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Photos	57	29.12	The CR has a physical description of the final CNSP. #1 orange capsules are listed but the MFR does not include a description of the capsule contents.	This has been updated.	09/09/24	Y	(Page 57) GRRX MFR_CR 090924
Clarification or Further Explanation	57	29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection). Per their process, they weigh 1-2 single capsules of a batch of 30-300 capsules as part of their quality control. However the CR	The pharmacy weighs 15 capsules of the 300 capsules made.	09/09/24	N	
Clarification or Further Explanation	57	29.15	Each CR is reviewed for completeness before the CNSP is released. Due to missing information as described in the above cells of this section.	The MFR/CR is reviewed for completeness before the CNSP is released.	09/09/24	N	
Photos	58	31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? If no, go to compliance statements. No	The label has been updated.	08/27/24	Y	(Page 61) GRRX Pt Label
Photos	58	31.1	information on the label is prominently and legibly displayed. Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or	The label has been updated.	08/27/24	Y	(Page 61) GRRX Pt Label
Updates/New SOPs or P&Ps	67	45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? If no, go to compliance statements.	A Quality Assurance SOP has been implemented and staff has been trained on their responsibilities.	08/28/24	Y	(Page 62) SOP 6.04 Quality Assurance Program
Updates/New SOPs or P&Ps	67	45.1	The pharmacy has a formal QA/QC program with documented activities. Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure	A Quality Assurance SOP has been implemented and staff has been trained on their responsibilities.	08/28/24	Y	(Page 62) SOP 6.04 Quality Assurance Program
Updates/New SOPs or P&Ps	68	45.3	The QA/QC programs address prevention and detection of errors and other quality problems. It appears there was no potency testing performed on the CNSP, or other evaluation, to assess their MFR prior to	trained on their responsibilities. Moving forward, all new MFRs will have potency testing performed prior to dispensing.	08/28/24	Y	(Page 62) SOP 6.04 Quality Assurance Program
Updates/New SOPs or P&Ps	70	49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? If no, go to compliance statements. Per process, none to date.	Recall procedures have been implemented and staff has been trained on their responsibilities.	08/28/24	Y	(Page 67) SOP 6.06 Recalling Compounded Prescriptions v1.1
Updates/New SOPs or P&Ps	70	49.1	The pharmacy has procedures to determine when recalls must be initiated. It is unclear when a subpotent CNSP is recalled.	Recall procedures have been implemented and staff has been trained on their responsibilities.	08/28/24	Y	(Page 67) SOP 6.06 Recalling Compounded Prescriptions v1.1
Clarification or Further Explanation	75	59.0	Final CNSP check observation: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs	The pharmacist performs a visual inspection of the CNSP to confirm all USP <795> requirements utilizing the updated MFR/CR.	09/09/24	N	
Clarification or Further Explanation	76	59.3	CNSP label was verified against the prescription or medication order. The pharmacy does not get a copy of the prescription for comparison purposes.	pharmacist will verify the CNSP label against the prescription or medication order.	09/09/24	N	
Photos	76	59.4	CNSP label was verified against the MFR. Batched CNSP are not labeled when placed in inventory. They are labeled during dispensing.	Batches are now labeled when placed into inventory.	08/27/24	Y	(Page 73) GRRX Batch Label
Photos	76	59.5	CNSP label was verified against the CR. Batched CNSP are not labeled when placed in inventory. They are labeled during dispensing.	Batches are now labeled when placed into inventory.	08/27/24	Y	(Page 73) GRRX Batch Label
Clarification or Further Explanation	77	59.7	All checks and inspection that are performed are properly documented. Pharmacist checks are not specifically documented on the CR other than the pharmacist's initials at the top of the CR.	Pharmacist checks are specifically documented now on the MFR/CR at the time of verification.	09/09/24	N	
Updates/New SOPs or P&Ps	77	61.0	Cleaning and Disinfection Observation: Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795>	compounding equipment is cleaned prior to compounding. SOPs and cleaning logs have been updated to reflect this.	08/28/24	Y	(Page 38) SOPF 3.02.01 Cleaning Log for Nonsterile Compounding v1.1

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FR4752437 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Specialty

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Rare Specialty Services LLC dba Rare Specialty Pharmacy

Physical Address: 398 W. Grand Avenue

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855.713.7049 Toll Free # (NAC 639.708, NRS 639.23286): 855.713.7049

Fax: 844.927.4665 Contact Email: info@rarespecialtyrx.com

Website: www.rarespecialtyrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Shama Patel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24470

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Shama Patel	NV Pharmacist Registration #: 24470
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
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Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Hector A. Herrera

Business Name: CASH&J LLC

Business Address: 114 W. Cliff Street

City: Somerville State: NJ Zip: 08876

Telephone: 908.296.2420 Email: hherrera@rarespecialtyrx.com

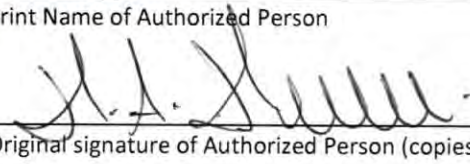
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Operating Officer (title) for Rare Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Hector A. Herrera

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

01/29/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Hector A. Herrera hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Operating Officer (title) for Rare Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 29 day of January, 2025

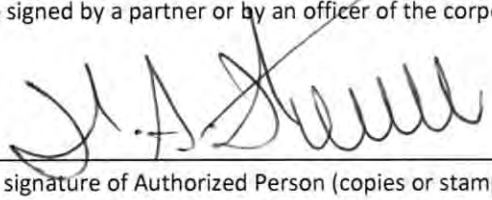
Michele A Esposito
Notary Public
State of New Jersey
My Commission Expires
August 16, 2029

Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hector A. Herrera

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

01/29/25

Date

Board Use Only	Date Received: 2/19/25	Amount: $500 ck 000029

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

RARE SPECIALTY SERVICES LLC
0451119765

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on April 26, 2024.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

HECTOR HERRERA
398 W GRAND AVENUE
RAHWAY, NJ 07065

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 14th day of January, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6160667983

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RARE SPECIALTY PHARMACY

Pharmacy/Wholesaler License # (if applicable) 28RS00802200

Physical Address 398 W GRAND AVENUE

City RAHWAY State NJ Zip 07065

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-713-7049 Website WWW.RARESPECIALTYRX.COM

Licensing Company Email INFO@RARESPECIALTYRX.COM

Section 2: Personal Information

First SHAMA Middle J Last PATEL

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City SOUTH BOUND BROOK State NJ Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ST. JOHN'S UNIVERSITY			09/04-05/10	
Address	**City**		**State**	**Zip**
8000 UTOPIA PARKWAY	JAMAICA		NY	11439
Diploma/Degree obtained, if any				
DOCTOR OF PHARMACY				

School Name			From - To (MM/YY – MM/YY)	
HERRICKS HIGH SCHOOL			09/00-06/04	
Address	**City**		**State**	**Zip**
100 SHELTER ROCK ROAD	NEW HYDE PARK		NY	11040
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
08/18-CURRENT		SOUTH BOUND BROOK	NJ	
From - To (MM/YY – MM/YY)		City	State	
08/00-08/18		ALBERTSON	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
RARE SPECIALTY PHARMACY			11/24-CURRENT	
Business Address	**City**		**State**	**Zip**
398 W GRAND AVENUE	RAHWAY		NJ	07065
Phone	**Title**		**Number of Employed Hours**	
855-713-7049	PHARMACIST IN CHARGE		680	
Description of Duties				
DISPENSING, DISTRIBUTION, COUNSELING, RECORD KEEPING RELATED TO PRESCRIPTION DRUGS				

Business Name			From - To (MM/YY – MM/YY)	
CVS PHARMACY			10/20-11/24	
Business Address	**City**		**State**	**Zip**
1520 FOREST AVENUE	STATEN ISLAND		NY	10302
Phone	**Title**		**Number of Employed Hours**	
			8320	
Description of Duties				
DISPENSING, DISTRIBUTION, COUNSELING, RECORD KEEPING RELATED TO PRESCRIPTION DRUGS				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, SHAMA J PATEL, certify that as the designated representative for

RARE SPECIALTY PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SP I am at least 21 years of age;
3. SP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SHAMA PATEL
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/04/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHAMA PATEL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/04/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Union

I, Michele A. Esposito, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/4/25

Date

Subscribed and Sworn to before me this 4 day of March 2025

Michele A Esposito
Notary Public
State of New Jersey
My Commission Expires
August 16, 2029

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Rare Specialty Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NJ 28RS00802200

Physical Address: 398 W. Grand Ave

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (855) 713-7049 Website: www.rarespecialtyrx.com

Licensing Company Email: HHERRERA@RARESPECIALTYRX.COM

Section 2: Personal Information

First: Hector Middle: A. Last: Herrera

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Somerville State: NJ Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University - Newark		09/07 - 05/10	
Address	**City**	**State**	**Zip**
195 University Ave, Newark, NJ	Newark	NJ	07102
Diploma/Degree obtained, if any			
Masters Degree Public Administration			

School Name		From - To (MM/YY – MM/YY)	
Rutgers Univesity - New Brunswick		08/00 - 05/02	
Address	**City**	**State**	**Zip**
57 US Highway 1	New Brunswick	NJ	08901-8554
Diploma/Degree obtained, if any			
Bachelors Degree Communication			

School Name		From - To (MM/YY – MM/YY)	
Middlesex County College		09/92 - 05/94	
Address	**City**	**State**	**Zip**
2600 Woodbridge Ave	Edison	NJ	08837
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Arthur L. Johnson High School		09/88 - 06/92	
Address	**City**	**State**	**Zip**
365 Westfield Ave	Clark	NJ	07066
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - present	[redacted]	Somerville	NJ	[redacted]
01/16 - 09/20		Newark	NJ	
01/08 - 01/16		Bound Brook	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Rare Specialty Pharmacy			04/2024 - PRESENT
Business Address	**City**	**State**	**Zip**
398 W. Grand Ave	Rahway	NJ	07065
Phone	**Title**		
855-713-7049	Chief Operating Officer		
Description of Duties			
Manage the day-to-day operations of Rare Specialty Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Borough of Bound Brook			04/2016 - 04/2024
Business Address	**City**	**State**	**Zip**
230 Hamilton Street	Bound Brook	NJ	08807
Phone	**Title**		
732-356-0833	Business Administrator		
Description of Duties			
Manage the day-to-day operations of the Borough of Bound Brook			

Business Name			From - To (MM/YY – MM/YY)
Borough of Peapack & Gladstone			12/2014 - 4/2016
Business Address	**City**	**State**	**Zip**
1 School St	Peapack	NJ	07977
Phone	**Title**		
(908) 234-2250	Business Administrator		
Description of Duties			
Manage the day-to-day operations of the Borough of Peapack & Gladstone			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HECTOR HERRERA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/4/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Union

I, Michele A. Esposito, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/4/25

Date

Subscribed and Sworn to before me this 4th day of March 2025

Michele A Esposito
Notary Public
State of New Jersey
My Commission Expires
August 16, 2028

Notary Public Signature

(Seal)

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
BOARD OF PHARMACY

HAS PERMITTED

RARE SPECIALTY PHARMACY
SHAMA J PATEL
398 W Grand Ave
Rahway NJ 07065

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

09/10/2024 TO 06/30/2025
VALID

28RS00802200
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

Cari Fais
ACTING DIRECTOR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR4752437	04-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-20-2024

RARE SPECIALTY PHARMACY
398 W GRAND AVE
RAHWAY, NJ 070653416

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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RARE SPECIALTY PHARMACY
398 W GRAND AVE
RAHWAY, NJ 070653416

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

Philip D. Murphy
Governor

TAHESHA L. WAY
Lt. Governor

Matthew J. Platkin
Attorney General

CARI FAIS
Director

February 4, 2025

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by RARE SPECIALTY PHARMACY to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that RARE SPECIALTY PHARMACY was issued a New Jersey registration 28RS00802200 on or about 09/10/2024 and is currently Active and in good standing with an expiration date of 06/30/2025. A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacy.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: RARE SPECIALTY PHARMACY (28RS00802200)

Address: 398 W. GRAND AVE

City: RAHWAY State: NJ Zip: 07065

I hereby authorize the NEW JERSEY to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant H.A. Herrera HECTOR A. HERRERA

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
28RS00802200	Active	09/10/2024	06/30/2025

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
Monique Evans	ASR4	NJ	2-4-2025	

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

MATTHEW J. PLATKIN
Attorney General

CARI FAIS
Acting Director

September 12, 2024

Masum Amin, RPIC
Rare Specialty Pharmacy
398 W Grand Ave
Rahway, NJ 07065

Re: Inspection Report # 8-7283-24-679
License # 28RS00802200

Dear Licensee:

Per your request, please find attached a copy of the New Jersey Board of Pharmacy (the "Board") inspection report for the pharmacy listed above. Because the Board may not have yet had the opportunity to review this report, please be aware the Board may determine that violations of law have occurred and determine to impose fines and penalties at a future date.

In addition, this report may contain confidential patient or licensee information. Before further distributing this report, please ensure that you are complying with laws regarding HIPAA requirements and those protecting Personally Identifiable Information (PII).

Sincerely,

Charles Akpan
Agency Services Representative
New Jersey Board of Pharmacy

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Enforcement Bureau
124 Halsey Street, 3rd Floor, Newark NJ 07102

MATTHEW J. PLATKIN
Attorney General

CARI FAIS
Acting Director

Mailing Address:
P.O. Box 45022
Newark, NJ 07101
(973) 504-6300

Anthony Rubinaccio, Executive Director
Board of Pharmacy

RE: MASUM AMIN, RPIC
RARE SPECIALTY PHARMACY-RAHWAY
ASSIGNMENT# 8-7283-24-679

Dear Mr. Rubinaccio,

Enclosed is a copy of a Report of Inspection, which is forwarded for Board review. This above captioned matter was assigned to Section 2 and I approved the report.

This assignment is now closed. No further action will be taken by the Bureau unless a new request is received.

Very Truly Yours,

Tony H. Qi

Tony H.Qi, Supervising Investigator
Section # 2

NO VIOLATION(S)

cc: Board of Pharmacy

Index of Exhibits and Attachments

1	List of ownership
2	One (1) site location map
3	Copy of the pharmacy floor plan specifications with dimensions
4	Statement from PIC for non-sterile hazardous compounding
5	Copy of Certificate from "Weights & Measures"
6	Copy of a "Certificate of Continued Occupancy" from the City of Rahway
7	Sample of prescription label with drug monograph
8	Pharmacy Personnel Identification Form
9	Copy of an alarm monitoring certificate from "Beacon Protection"
10	Copies of Temperature Logs
11	Copy of Temperature Policy & Procedures
12	Copy of "Certificate of Formation"
13	Copy of "Certificate of Authority"
14	Copy of "Certificate of Liability Insurance"
15	Copy of State of New Jersey Business Registration Certificate
16	Copy of Department of Treasury-Internal Revenue Service
17	Copy of "Certificate of Alternate Name"
18	Statement from PIC PHI storage

Index of Exhibits and Attachments

Attachments

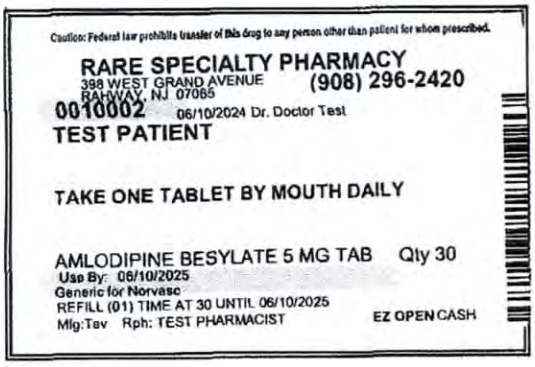
Attachment A: New Pharmacy Booklet

Attachment B: Pharmacy Permit Application + Photographs + New Pharmacy Supplemental Checklist

Attachment C: Statement from PIC Masum Amin and permit holder Hector Herrara that adjacent rooms will be used to store PHI.

NEW PHARMACY
BOARD OF PHARMACY
INSPECTION CONDUCTED
IN CONNECTION WITH A PERMIT APPLICATION FOR A

New
(Retail)
Pharmacy


Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

RARE SPECIALTY PHARMACY
398 WEST GRAND AVENUE (908) 296-2420
RAHWAY, NJ 07065
0010002 06/10/2024 Dr. Doctor Test
TEST PATIENT

TAKE ONE TABLET BY MOUTH DAILY

AMLODIPINE BESYLATE 5 MG TAB Qty 30
Use By: 06/10/2025
Generic for Norvasc
REFILL (01) TIME AT 30 UNTIL 06/10/2025
Mfg:Tev Rph: TEST PHARMACIST EZ OPEN CASH

Board of Pharmacy please note:
The "Pharmacy Permit / CDS License Approval Notification Letter"
is to be:

☑ Mailed to ☐ Faxed to:

Name and Title: Hector Herrera Name: _____

Address: 398 W Grand Street Title: _____

_____ Fax Number: _____

City, State, Zip: Rahway, NJ 07065 Email HHerrera@RareSpecialtyRx.com

Revised: 10/2005
:ef

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ENFORCEMENT BUREAU

REPORT OF INSPECTION

TO: Board of Pharmacy	FILE # #8-1283-24-679	DATE 6/20/2024
SUBJECT: Rare Specialty Pharmacy 398 W Grand Ave Rahway NJ 07065 Masum Amin RPIC 28RI03560800		BY: Kapetanakis R.P./Field Representative

REFERENCE:

New pharmacy inspection conducted pursuant to N.J.A.C. 13:39-4.1.

ASPECTS OF THIS INSPECTION MERITING CONSIDERATION:

☐	I	Ownership
☐	II	Location/Proposed Operations
☐	III	Spatial Requirements/Physical Facilities
☐	IV	Storage Facilities
☐	V	Required Signs and Placards
☐	VI	Library
☐	VII	Metrological Equipment
☐	VIII	Dispensing Complements
☐	IX	Record-keeping & Patient Counseling

☐	Enclosed as Attachment #1 is a copy of the filed "Application For Permit to Conduct a Pharmacy" which predicated this inspection.

DETAILS:

A. N.J.S.A. 45:14-75 - Requires that all businesses or enterprises that operate a pharmacy, drug store or render such professional services be registered with and be issued a permit by the Board of Pharmacy. The terms "pharmacy" and "drug store" are defined as establishments or places of business that are required to be operated or managed at all times by registered pharmacists. To satisfactorily conduct a practice of pharmacy, the Board has enacted appropriate rules and regulations that establish minimum standards in regard to: equipment, supplies, physical space, hours of operation and other requisites that may be essential to compound and dispense prescription items for the purpose of offering adequate pharmaceutical services to the public.

B. N.J.S.A. 45:14-70 - Directs, in part, that only upon application on a form prescribed and furnished to the Board, will the Board consider and issue a permit to conduct a new pharmacy.

C. N.J.A.C. 13:39-4.1 - Details: the progression, eligibility and requisites involved in the new pharmacy permit application process, namely:

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to, but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the names and addresses of the owners and operators, if a sole proprietorship or partnership; the names and addresses of all officers and stockholders, and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is a non-publicly held corporation; and the names and addresses of the officers, if a publicly held corporation.

(d) The permit application shall include the name of the pharmacist-in-charge, who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person or other business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, state or federal law pertaining to the practice of pharmacy or the dispensing or controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

D. Consistent with the dictates of N.J.S.A. 45:14-75, N.J.S.A. 45:14-70 and N.J.A.C. 13:39-4.1, this inspection booklet is designed to place at the Board's disposal, a uniform, systematic, comprehensive presentation of all of the data that is essential for the Board to equitably evaluate and consider the applicant's potential compliance with the regulatory requisites as well as to satisfactorily conduct a practice of pharmacy. As required by N.J.A.C. 13:39-4.1, it is the applicant's responsibility and obligation to have available for transfer to the Inspector, all the necessary ownership organizational charts, site location specifics and floor plan specifications with accurate dimensions. For those pharmacies that have unusually complex ownership structures, or are to be located in sensitive areas that may adversely impact upon the pharmacy operations, (the Board, in advance of the inspection) will notify the applicant of the additional information that will be required. The applicable sections of the booklet allow for the notification of the presence of any specially requested information, that will be annexed hereto. An index of this report exhibit's attachments appears is enclosed.

E. To assist in the verification that all of the required information has been acquired, the booklet is divided into sequential categories that are designated as follows: Category I - Ownership, Category II - Location/Proposed Operations, Category III - Spatial Allocations and Physical Facilities, Category IV - Storage Facilities, Category V - Required Signs and Placards, Category VI - Library, Category VII - Metrological Equipment, Category VIII - Dispensing Complements, Category IX- Record-keeping and Patient Counseling Requisites. (For those pharmacies that are licensed as a "Pharmacy Department," inspection activity will include a pharmacy department compliance checking procedure form which will be included as an exhibit attachment to this report).

F. When documenting the informational requests contained on the following pages, the inspector places either an "X" or "✓" to indicate non-compliance with that particular statutory requirement. To denote that an inspection activity has been undertaken regarding each of the categories which encompass this inspection procedure, the initials of the inspector and/or inspection party will be placed adjacent to each category of inspection procedure denoted by roman numeral.

G. Prior to departing from the pharmacy, the inspector explains and discusses with the applicant, any deficiencies that may be noted. To avoid any possible future misunderstandings, the applicant is requested to acknowledge through the recording of initials, the deficiencies that were noted in connection with the inspection. The applicant is also invited to add written comments in areas that are provided in the "Comments" section at the bottom of each segment of the inspection "Acknowledgment" portion of this report. Upon the inspector's departure from the pharmacy, a copy of the inspection report's findings is left with the inspected party.

H. New pharmacy inspection procedures are outlined below:

(a) The applicant or their authorized representative or representatives who are present for the inspection, complete pharmacy employee/representative Personnel ID Sheets.

(b) The applicant or authorized representative verifies the accuracy of the information reported on the "Application For Permit To Conduct A Pharmacy" and records, dates and initials any changes made to the copy of the submitted application which is included with this report as an exhibit. If no changes are to made to the Permit Application, the applicant will either "X" or "✓" and initial the statement: "My review of the responses that had been previously recorded in reply to the informational requests of the "Application For Permit To Conduct A Pharmacy" forms are correct, and all declarations remain as reported".

FILED "NEW PHARMACY" APPLICATION REVIEW

☐ My review of the responses that had been previously recorded in reply to the informational requests of the "Application For Permit to Conduct A Pharmacy" forms are correct, and all declarations appear accurately reported.

☐ Changes and/or modifications were required to be made to the filed "Application For Permit To Conduct A Pharmacy." See Attachment #1 for specifics.

[redacted]

Inspection revealed deficiencies regarding the pharmacy's ownership. (13:39-4.1) Yes ☐ No ☐ (If answered affirmatively, see "Comments" which follow for specific information)	☐ "Y"

A. An ownership organizational chart is attached. ☐*

B. Documentation reflecting a complex ownership structure that requires special consideration is attached. ☐*

C. A supplemental report explaining the ownership structure intricacies is attached. ☐*

Item	Comments
A.	A list of the ownership chart is attached as Exhibit #1

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

LOCATION/PROPOSED OPERATIONS

Inspection revealed deficiencies regarding the subject pharmacy's location and/or proposed operations (13:39-4.1(b)) ☐*	☐ "V"

A. A site location, that displays the exact intended location of the pharmacy and all contiguous premises (but not necessarily a Part of the pharmacy) is attached. ☐*

B. The pharmacy is located in a sensitive area that may adversely impact upon the access, egress and the operations of the pharmacy (13:39-5.2). ☐*

C. A supplemental report explaining the proposed operations is attached. ☐*

Item	Comments
A.	A site location map is attached as Exhibit #2

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

THE SPATIAL REQUIREMENTS/PHYSICAL FACILITIES

A. The pharmacy's floor plan specification with accurate dimensions is attached. ☐*		
B. AREA (13:39-5.4(b)) - Occupies a minimum of 150 square feet. OK		☐ "V"
C. PRESCRIPTION COUNTER(S) (13:39-5.5) - Not less than 12 total feet in length and 18 inches in width. OK		☐ "V"
D. SINK (13:39-5.6) - Is easily accessible to the prescription counter, and is equipped with both hot and cold running water. OK		☐ "V"
E. SHELF, DRAWER or CABINET SPACE (13:39-5.7) - Is sufficient for the storage of prescription drugs, chemicals and required equipment.		☐ "V"
F. CERTIFICATE OF OCCUPANCY - A "Certificate of Occupancy" has been issued by the local building authorities. ☐* OK		☐ "V"

Item	Comments
A.	A copy of the pharmacy's floor plan specifications is attached as Exhibit #3
B.	A Copy of the Certificate of Occupancy Continued City of Rahway is attached as Exhibit #6

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

A. A satisfactorily operational refrigerator is present (13:39-5.8(a)12). OK	☐ "√"
B. Controlled substances are to be satisfactorily stored; i.e.: if not dispersed throughout the pharmacy's drug stock inventory, there is an adequately secured and safeguarded storage area for controlled dangerous substances (13:39-5.8(a)4). OK	☐ "√"

Item	Comments
	Schedule CII Controlled dangerous substances (CII CDS) will be stored in a minimally secured cabinet that can be opened with a key.
	CII-CV CDS will be dispersed throughout the Active drug stock.

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

V. RECOMMENDATIONS/DEFICIENCIES

A. There is present on the building's exterior, a sign that identifies the presence of a pharmacy at the location (13:39-5.3(a)). ☐* OK	☐ "V"
B. Drug Utilization Review Council placards are posted in two locations (13:39-5.8(a)17). OK	☐ "V"
C. A sign with the name of the R.P.-in-charge is displayed (13:39-5.3(b)).	☐ "V"
D. "Smoking Prohibited" signs are posted (26:3D-42). OK	☐ "V"

Item	Comments
C.	Signage on the door is not permanent Signage of hours OR PIC name NO Signage on door entrances that indicate a pharmacy is present
	* Email sent on July 21 with permanent Signage on front door entrance and back door exit

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

A. Current editions of suitable reference texts for the below-indicated categories are present (13:39-5.8(a)1): ☐ "Y"

1. Comprehensive
2. General Practice of Pharmacy.
3. Drug Interactions.
4. Drug Product Composition.
5. Patient Counseling.

OK

Listing of Texts Present: Facts and Comparisons digital version.

(Title and Edition/Publication Date) Pharmacotherapy A pathophysiologic Approach 11th Edition hard copy books.

B. The current "Drug Utilization Review Council" Formulary (and supplements, if any) is present (13:39:5.8(a)17). ☐ "Y"

Invoices were present at the location reflecting "library texts" on order. Yes ☐ No ☐ ☐*

Item	Comments

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

VII. METROLOGICAL EQUIPMENT

A. A Class "A" prescription balance or equivalent electronic device is present (13:39-5.8(a)5). Make: Torbal Model Nr: DRG-402-320 Serial Nr: 703344	☐ "V"
B. A satisfactory set of metric weights is present (13:39-5.8(a)5). 1. Denominations: 50mg (_), 100mg (_), 200mg (_), 500mg (_), 1Gm (_), 2Gm (_), 5Gm (_), 10Gm (_), 20Gm (_), 50Gm (_) OK	☐ "V"
C. Volumetric devices capable of measuring from 0.3ml to 500ml are present (13:39-5.8(a)6). 1. Capacities: 10ml (_), 25ml (_), 50ml (✓), 100ml (✓), 250ml (_), 500ml (_). 2. Glass graduates of a capacity greater than 15 milliliters (4 fluid ounces) [may be double scale and may be of either a cylindrical or conical design] are present. Graduates of a capacity of 15 milliliters or less, [limited to single-scale and cylindrical design] are present. OK (In lieu of graduates of less than 15 milliliter capacities, the Board will accept syringes, pipettes or other acceptable volumetric measuring devices. Present? ☐	☐ "V"
D. All metrological equipment (balances, scales, weights and automatic counting devices) have been inspected and Sealed by the appropriate Department of Weights and Measures (13:39-5.11). Inspected and sealed on: 5/17/2024 (Date) OK	☐ "V"

Invoices were present at the location reflecting equipment" on order. Yes ☐ No ☐ ☐*

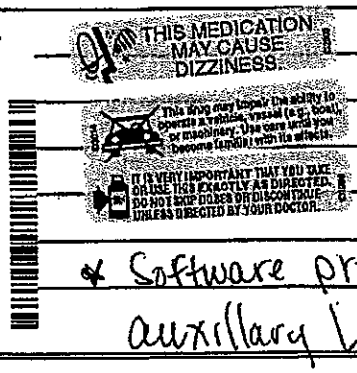
Item	Comments
A.	The Class A prescription balance in use was an electronic Balance
B.	A copy of the "Certificate of Inspection" for weights and measures is attached as Exhibit #5.

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

VIII. DISPENSING COMPLEMENTS

A.	An over-the-counter "Schedule V CDS" record book (13:39-5.8(a)2) is present, if the pharmacy dispenses such medication without a prescription. Does not intend to sell CV OTC	☐ "V"
B.	A device to permanently file prescriptions (13:39-5.8(a)3) is present. OK	☐ "V"
C.	Prescription labels, which upon dispensing, contain the name, address and telephone number of the pharmacy (13:39-7.12(a)1 and 2)(13:39-5.8(a)14) are present. (An exemplar is attached. ☐*) OK	☐ "V"
D.	Auxiliary labels, to include poison labels (13:39-5.8(a)15) are present. (Exemplar attached. ☐*) OK	☐ "V"
E.	A glass mortar and pestle (minimum of one) is present (13:39-5.8(a)7). OK	☐ "V"
F.	Glass funnels are present (13:39-5.8(a)8). OK	☐ "V"
G.	Stirring rods are present (13:39-5.8(a)9). OK	☐ "V"
H.	Spatulas (minimum of one steel and one composition) are present (13:39-5.8(a)10). OK	☐ "V"
I.	Ointment Tile or parchment pad is present (13:39-5.8(a)11). OK	☐ "V"
J.	An approved counting device or counting tray is present (13:39-5.8(a)13). OK	☐ "V"
K.	A suppository mold is present (13:39-5.8(a)16). N/A	☐ "V"

Invoices were present at the location reflecting "dispensing complements" on order. Yes ☐ No ☐ ☐*

Item	Comments
	Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed. RARE SPECIALTY PHARMACY 398 WEST GRAND AVENUE (908) 296-2420 RAHWAY, NJ 07065 0010002 08/10/2024 Dr. Doctor Test TEST PATIENT TAKE ONE TABLET BY MOUTH DAILY AMLODIPINE BESYLATE 5 MG TAB Qty 30 Use By: 08/10/2025 Generic for Norvasc REFILL (01) TIME AT 30 UNTIL 08/10/2025 Mfg:Tev Rph: TEST PHARMACIST EZ OPEN CASH  * Software prints auxillary labels

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

A Patient Profile Record system is in place (13:39-7.19(a)). OK		☐ "Y"
1. The Pharmacy will use a "Manual" Profile Record Keeping System. An exemplar of the form to be used is attached. ☐*		
2. The pharmacy will use an electronic record keeping system that is equipped with Software supplied by Pioneer Rx.		
B Patient Counseling system (13:39-7.19(e)) et. seq.		
1. There is in place a system where patients refusals to accept offers to counsel will be documented (13:39-7.19(e)3). ☐* OK POS		☐ "Y"
2. For those situations when neither the patient nor the care-giver is physically present, the offer to counsel will be extended (13:39-7.19(e)4) satisfactorily:		☐ "Y"
a. By telephone. ☑		
b. Through a printed notification ☐*, that:		
(1) Is printed in a bold, easily read print.		
(2) Is printed on a separate document that will accompany the prescription.		
(3) Will include:		
(a) The hours that the pharmacist will be available.		
(b) The telephone number where the pharmacist will be able to be reached.		
(c) The telephone number is local or will be at no cost to the pharmacy's projected primary patient population.		

Item	Comments
	POS system through pioneer Rx
B-1	Customers refusal and acceptance of pharmacists offer to counsel will be recorded electronically via POS.

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

NEW JERSEY BOARD OF PHARMACY

-REPORT OF INSPECTION ACKNOWLEDGMENT-

Name of Pharmacy: Rare Specialty ~~Rx~~ Pharmacy

Address: 398 W. Grand Avenue
Rahway NJ 07065

Name and registration number of pharmacist-in-charge.

Masum Amin RPC 28RI03560800

(If pharmacist-in-charge is not present, enter name and original R.P. Certificate Number of R.P. on duty)

This is to verify that I have been present during this inspection, and with the exceptions noted in the "comments" below, I acknowledge the existence of the deficiencies that are cited on the appropriate pages of this booklet.

COMMENTS:

X Masum Amin
SIGNATURE OF PHARMACIST IDENTIFIED ABOVE

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, PO Box 45013,
Newark, NJ 07101
(973) 504-6450

Pharmacy Permit Application

Please print clearly

Pursuant to N.J.S.A. 45:14-40, I or we, HECTOR A. HERRERA, hereby make application for a permit to conduct the pharmacy referred to below until June 30th next, and certify to the correctness of the following information:

(Please check the appropriate box below. List the present owner or address where applicable.)

- ☐ Transfer of ownership from _____
- ☐ Change of location from _____
- ☐ Remodeling
- ☒ New pharmacy

1. (a) Name under which pharmacy is to be operated: RARE SPECIALTY PHARMACY
   (b) Is the above name registered in the office of the county clerk? ☐ Yes ☐ No
   (c) Telephone number: 908-296-2420 (Include area code)
   (d) 398 W. GRAND AVE (Street address of pharmacy) IRVING (Nearest cross street)
   RAHWAY (City) NJ (State) 07065 (ZIP code) UNION (County)

2. Type of permit: ☒ Retail ☐ Institutional
   Type of practice(s) in which the pharmacy is to engage: (Check all that apply.)

☐ Standard retail pharmacy	☐ Retail pharmacy department	☐ Long-Term Care pharmacy
☐ Mail order pharmacy	☐ Nuclear pharmacy	☐ Sterile admixture retail
☐ Hospital pharmacy	☐ Hospital satellite pharmacy	☒ Specialty pharmacy
☐ Other, please indicate: _____		

3. If application is **not** being made for a corporation, list below the names and addresses of individuals, partners, trustees, receivers, executors or other persons in whom ownership will be vested.

Full name of owner	Home address	Percentage of ownership	R.Ph. License Number
HECTOR A. HERRERA	114 W. CLIFF ST. SOMERVILLE NJ	08876 100%	NA
Full name of owner	Home address	Percentage of ownership	R.Ph. License Number
Full name of owner	Home address	Percentage of ownership	R.Ph. License Number

4. If application is being made for a corporation, complete the information requested below:

   (a) _____ (Name and address of registered agent of the corporation)

   (b) Date of incorporation: _____

   (c) Is the corporation's stock: ☐ publicly traded; or ☐ nonpublicly traded?

Names and addresses of all officers and owners of 10 percent or more of stock

(d) President _____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

(e) Vice Pres. _____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

(f) Secretary _____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

(g) Treasurer _____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

(h) Others _____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

_____
Name of officer | Home address | Percentage of stock | R.P. Certificate Number

5. Fill in the information requested below for all of the Registered Pharmacists to be employed at this pharmacy. List the Pharmacist-in-Charge in line (a) below:

(a) (in charge) MASUM AMIN | 40 | 28RI03560800
Full name of Registered Pharmacist | Hours employed per week | Original Certificate Number

(b) _____
Full name of Registered Pharmacist | Hours employed per week | Original Certificate Number

(c) _____
Full name of Registered Pharmacist | Hours employed per week | Original Certificate Number

(d) _____
Full name of Registered Pharmacist | Hours employed per week | Original Certificate Number

(e) _____
Full name of Registered Pharmacist | Hours employed per week | Original Certificate Number

6. Hours: This pharmacy will be open a total of 40 hours per week.
Open weekdays from 9 a.m. to 5 p.m. Open Sundays from — a.m. to — p.m.
Open Saturdays from — a.m. to — p.m.
Hours to be closed for meals or other exceptions (other than major U.S. holidays) —

7. Pharmacist-in-Charge MASUM AMIN 35 KARRICH COURT MONROE NJ 08831 240 731 0922
Name | Address | Home telephone number (include area code)

8. Are there any pending indictments of any nature or any alleged violations of the laws governing the practice of pharmacy, dispensing narcotics, alcohol, hypnotic or other regulated drugs against any of the individuals listed in items three, four, and five of this application, or have any of them been convicted of any crime within the past 10 years? (Attach additional sheets if needed.) ☐ Yes ☒ No
If "Yes," give details. _____

9. Paste a copy of your prescription label and a copy of your poison label in the spaces indicated below:

(If labels are not available, they can be supplied separately as soon as they are available.)

10. Please provide the name of supportive personnel and all other unregistered employees connected with prescription and drug departments. If none, write "None." (Attach an additional list if more space is needed.)

NONE
Full name | Home address | Hours employed per week

_____
Full name | Home address | Hours employed per week

11. How many pharmacies do you operate in New Jersey? 0 (Attach list of any additional pharmacies.)

Pharmacy name	Address
Pharmacy name	Address
Pharmacy name	Address

12. (a) Date upon which a change of ownership, moving to a new location or opening or remodeling of a pharmacy is anticipated: ASAP

(b) Date premises will be ready for inspection: (If the ready date for inspection changes for any reason, the Board of Pharmacy must be notified, in writing, in a timely manner.) ASAP

The information requested below, regarding the specifications, equipment and facilities of the prescription area, must be filled in completely.

13. Floor dimensions of the pharmacy. Please give the length and width including the portion occupied by the prescription area, but not including stock and storage rooms. Length: _____ Width: _____

14. Floor dimensions of the prescription department including space occupied by fixtures. Length: 28' Width: 16'

15. Width of prescription counter, free of overhanging shelves: 3' Total length of counters: 27'

16. We now possess or have ordered the equipment as outlined in the Board of Pharmacy Regulations. ☒ Yes ☐ No

(Note to purchasers of existing pharmacies: you are to note below the equipment as outlined in the Board of Pharmacy Regulations which is not now available in your pharmacy. At the time of your inspection, you must show a purchase order for the missing equipment.)

17. The outline on page four of this application is a true representation of the dimensions of the pharmacy setting forth, in detail, the prescription department fixtures.

Affidavit

18. Affidavit A, below, must be completed by the owner, or a partner, as listed in item three on page one or by a principal officer as listed in item three or four on page one if the pharmacy or drug store is owned by a corporation. If the person executing Affidavit A is not also the Registered Pharmacist-in-Charge of the pharmacy or drug store, then the Registered Pharmacist-in-Charge must complete Affidavit B.

Each Affidavit must be sworn to before a Notary Public or other authorized officer.

I do solemnly swear and affirm that the answers and statements made in this form are true and correct to the best of my knowledge and belief, and that the prescription area of this pharmacy has all of the equipment and facilities with the exceptions noted on this application, which will be obtained immediately, and meets all of the specifications enumerated in the "Prescription Area Regulations" a copy of which I have seen. In the event of loss or breakage of any item on the equipment list, it will be replaced promptly. I also agree to display the permit and understand that the permit is not transferable and agree to return it to the Board upon request. If I should move, sell or discontinue this pharmacy or if it is damaged by fire or by any other occurrence at any time, I agree to notify the Board of Pharmacy immediately. **Affidavit "A" must be executed on every application.**

Affidavit "A"

(see item 18 above)

RARE SPECIALTY PHARMACY

Name of pharmacy (if a corporation, give exact legal title)

Signature (circle title below)

owner, partner, trustee, receiver, lessee, executor, president, secretary

Subscribed and sworn to before me this 23rd day of April A.D. 2024

Notary's signature

My commission expires 2/7/27

CHRISTINA ABREU
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 2416998
MY COMMISSION EXPIRES FEB. 07, 2027

Affix Seal Here

Corporation Seal (if any)

Affidavit "B"

(see item 18 above)

Signature of Registered Pharmacist-in-Charge

Subscribed and sworn to before me this 24th day of Apr. A.D. 2024

Notary's signature

My commission expires 02/01/2027

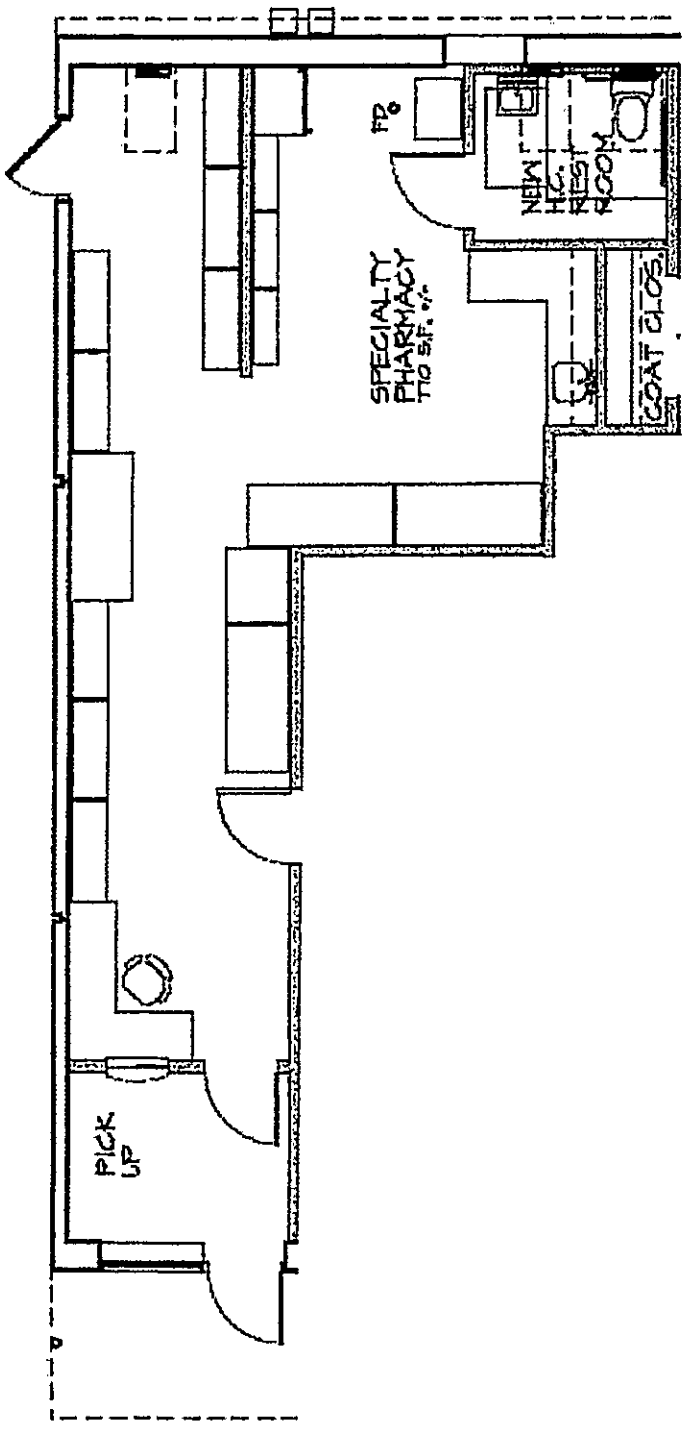
LAUREN N. BARONE
Notary Public, State of New Jersey
My Commission Expires 02/01/2027

Affix Seal Here

To Notary Public: Please make sure that the person taking the oath has read all of item 18.

Draw an outline of the floor plan of the pharmacy, including the prescription area and stockrooms, on this page. If the length of the room is less than 72 feet, consider each square as measuring two feet on each side. If the length of the store exceeds 72 feet, consider each square equivalent to four feet on each side. Indicate the space allotted to each department according to scale. Use ink when making the sketch, if possible. Please use a ruler in making the drawing.

Outline prescription area fixtures in detail with dimensions.


FD
NEW H.C. REST ROOM
SPECIALTY PHARMACY
710 S.F. +/-
COAT CLOS.
PICK UP

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, PO Box 45013,
Newark, NJ 07101
(973) 504-6450

Affidavit "C"

All questions must be answered and forwarded to the Board of Pharmacy together with the Application for Renewal of Registration and Permit to Operate a Pharmacy. No renewal permit will be issued without a signed and dated Affidavit "C," which will be affixed to and become a part of the Application for Renewal of Registration and Permit to Operate a Pharmacy. Answer all of the questions completely.

Please check "Yes" or "No."

1. Does any physician(s), or other person(s) authorized to write prescriptions in the State of New Jersey, possess any financial interest, direct or indirect, in the pharmacy? ☐ Yes ☒ No
2. Does any physician(s), or other person(s) authorized to write prescriptions in the State of New Jersey, possess any lease-hold interest, direct or indirect, in the pharmacy? ☐ Yes ☒ No
3. Does any physician(s), or other person(s) authorized to write prescriptions in the State of New Jersey, own or possess any interest, direct or indirect, in the building in which the pharmacy is located? ☐ Yes ☒ No
4. Are there any outstanding loans, to or from, physician(s) or other person(s) authorized to write prescriptions in the State of New Jersey? ☐ Yes ☒ No
5. If the answer to any of the above is "Yes," kindly answer the following questions. Please type or print clearly.
   a. Is the physician(s) or other person(s) practicing in the trading area of this pharmacy? ☐ Yes ☐ No
   b. Name and address of the physician(s) or other person(s):

   _____

   _____

   _____

   c. Extent and description of the financial interest. Please provide a full explanation:

   _____

   _____

   _____

   _____

I certify that the statements made by me on Affidavit "C" are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

RARE SPECIALTY PHARMACY
Name of pharmacy (If a corporation, give the exact title)

4/23/2024
Date

Signature of owner or officer

Title (check one): ☒ Owner ☐ Partner ☐ President ☐ Secretary ☐ Treasurer

Affidavit Regarding Internet and/or Mail Order Pharmacy Activity

This matter was opened to the New Jersey State Board of Pharmacy by application of RARE SPECIALTY PHARMACY to operate a pharmacy in the State of New Jersey. The applicant, who may engage in Internet and/or mail order pharmacy activity under a retail permit granted pursuant to the signature on this Affidavit, has agreed to the following conditions prior to commencing either or both of the above-listed services:

1. RARE SPECIALTY PHARMACY is hereby granted a retail permit to operate a pharmacy in the State of New Jersey, subject to the following ongoing conditions set forth in paragraphs 2 through 4 below.

2. RARE SPECIALTY PHARMACY ("applicant") shall obtain the National Association of State Boards of Pharmacy Verified Internet Pharmacy Practice Site Certification prior to engaging in Internet or online dispensing.

3. The applicant shall make all reasonable efforts to ensure that all prescriptions received via the Internet, or by mail, are valid, to wit, there exists a prescriber-patient relationship and that a reasonable and prudent pharmacist would believe that the patient has been physically examined by the prescriber or the collaborating physician. The applicant shall not accept any prescription for dispensing where he knows or should have known that the prescription has been written pursuant to an online diagnosis or survey by a prescriber.

4. The applicant shall not act as a facilitator of prescriptions being transferred by the Internet or by mail to any pharmacy in or outside of the United States that he knows or should have known dispenses in violation of the conditions set forth in Paragraph 3 of this Affidavit. This paragraph shall not preclude the routine transfer of the prescription as requested by the patient as authorized by State and federal law.

Affidavit of Applicant

I, HECTOR A. HERRERA, agree being duly sworn, depose and say under penalty of false statement, I am the party described as above; that the information given in this Affidavit and submitted materials contain no willful misrepresentations and that the information is true and complete. I understand that should an investigation at any time disclose otherwise, I may face legal sanctions. I understand that in signing this Affidavit, I am consenting to any reasonable inquiry that may be necessary to verify the information I have provided in this document.

Applicant's Full Signature — Date: 4/23/2024

Notary's Full Signature — Date: 4/23/24

Notary's Commission Expires: 2/7/27

CHRISTINA ABREU
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 2416998
MY COMMISSION EXPIRES FEB. 07, 2027

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU
NEW PHARMACY SUPPLEMENTAL CHECKLIST
(completed in connection with a new pharmacy permit application)

Rare Specialty Pharmacy
Name of Pharmacy

398 W Grand Ave
Street Address

Rahway NJ 07065
City, State, Zip

6/20/2024
Date of Inspection

Kapetanakis
Investigator

Pharmacy Representative

Bureau File #: 8-7283-24-679

Name of RPIC: Masum Amin RPIC
25RPI03560800

	Yes	No	Exhibit
Does the pharmacy intend to have shared services with any other facilities, including with those under the same ownership?	☐	X	☐
Does the pharmacy intend to engage in dispensing non-patient specific prescriptions or dispensing for prescriber office use?	☐	X	☐
Does the pharmacy intend to engage in internet dispensing or telepharmacy / telemedicine services?	☐	X	☐
Does the pharmacy intend to conduct non-sterile componnding that involves in hazardous drugs and/or chemicals including hormones and biologics?	☐	X	☐
Does the pharmacy have a contingency plan in the event the pharmacy cannot be secured for medications and prescription files?	☐	☐	☐
Does the pharmacy have the means to conduct daily PMP reporting?	X	☐	☐
Does the pharmacy have a security system equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or is disabled?	X	☐	☐
Does the pharmacy have the means to maintain and document room temperature between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit) and refrigerator temperature between 2 and 8 degrees Celsius (36 and 46 degrees Fahrenheit) for proper storage prescription drugs and chemicals? Continuous monitoring temp and manually monitoring	X	☐	☐

Does the pharmacy intend to handle expired medications via a reverse distributor or internal destruction of expired/damaged/returned medications?

Specify: N/A

List the names of the wholesalers and/or distributors that the pharmacy intends to purchase medications from:

N/A

COMMENTS: PMP reporting daily via Pioneer Rx Software.

Beacon Alarm Services Backup Battery

Masum Amin
Name of Pharmacist (print)

Signature of Pharmacist

Investigator Signature:

Rare SP Ownership

RARE
SPECIALTY PHARMACY

June 10, 2024

To whom it may concern:

Rare Specialty Pharmacy will not be participating in compounding non-sterile hazardous products.

Sincerely,

Masum Amin, PharmD, CSP
Pharmacist in Charge
Rare Specialty Pharmacy

New Jersey Office of the Attorney General
Division of Consumer Affairs
Office of Weights and Measures
P.O. Box 490, Avenel, New Jersey 07001
Phone (732) 815-7826 • Fax (732) 382-5298

Registration Application for Commercial Weighing and Measuring Devices

1. Please indicate registration status. Please check box below.

New ☒ Renewal ☐ Indicate year: 2024

Registration number: _____
If unknown, please leave blank. A number will be assigned.
Date issued: _____
Return by: _____

Business location - Please print or type.

Rahway (City) Union (County)

2. Device location - Please print or type.

Rare Specialty Pharmacy (Company name)

398 W. Grand Ave. (Street address) Rahway (City) NJ (State) 07065 (ZIP code) Union (County)

_____ (Representative) _____ (Telephone number (include area code)) _____ (Fax number (include area code))

3. Mailing address - Complete if different from above.

_____ (Company name)

_____ (Street address) _____ (City) _____ (State) _____ (ZIP code) _____ (County)

_____ (Representative) _____ (Telephone number (include area code)) _____ (Fax number (include area code))

4. List device information in chart below. See reverse side for device type, fees and important information.

	For Official use only Jur Code	Type of device	I.D. number	Model number	Serial number	Manufacturer's name	Capacity scales & meters only	Number of Hoses (Metering devices) *If applicable*	Amount due
1		scale	01	DRX-4K2-320	703344	Torbal	320g		$ 25.00
2		Pharmaceutical weight kit	02		35633	Troemner	–		$ 40.00
3									
4									
5									
6									
7									
8									
9									
10									

Please make check or money order payable to Weights & Measures Fund.
Mail to: Office of Weights & Measures, PO Box 490, Avenel, NJ 07001
Note: No action will be taken without a completed application and the payment of appropriate fees.

Total amount due: $ 65.00
Late fee-add $10 for each device: + —
Grand total: $ 65.00

I hereby certify that the above information is true.

Signature: _____ Date: _____

For Official Use Only/Comments:

STATE OFFICE COPY

New Jersey Office of the Attorney General
Division of Consumer Affairs
Office of Weights and Measures
1261 Routes 1 & 9 South
Avenel, New Jersey 07001
(732) 815-4840

Date: _____

Registration number: _____

Jurisdiction: _____

Certificate of Inspection and Test
Small and Medium Capacity Scales

THIS IS TO CERTIFY, that in accordance with the laws of the State of New Jersey, I have inspected and tested the weighing equipment herein described, said to be the property of:

Name: _____ Trading as: _____

Address: _____
Street City State ZIP code

Telephone number: _____
(Include area code)

with the following results:

	Scale type	Manufacturer	Model number	Serial number	Capacity	Min. Grad.	Tolerance		Check the appropriate action taken
							Maint.	Accept.	
1									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
2									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
3									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
4									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
5									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
6									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
7									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed
8									☐ Sealed ☐ Sealed Subject ☐ Condemned ☐ Not sealed

	App. Weight	Indicated Weight	App. Weight	Indicated Weight	App. Weight	Indicated Weight	App. Weight	Indicated Weight
1								
2								
3								
4								
5								
6								
7								
8								

Remarks: _____

_____
Weighing equipment user

_____
Inspector of Weights and Measures Officer

WEIGHING EQUIPMENT USER COPY

City of Rahway
Department of Code Enforcement
Division of Property Maintenance

Certificate of Approval for Continued Occupancy

Property located at 398-406 W GRAND AVENUE, (398), RAHWAY, NJ 07065

Block 164 **Lot** 18

Premises to be Occupied as RETAIL PHARMACY

This Certificate is issued to RARE SPECIALTY PHARMACY C/O HECTOR HERRERA

Date Issued MAY 30, 2024

CERTIFICATE # CECERT-05-24-327

Frank Spallone, MB.

Frank Spallone
Director of Code Enforcement

Fee $200.00 **No. of units** 1

The inspection for Smoke and CO detectors is included with this CACO for properties of 2 units or less. Properties with 3 units or more will need a separate Fire Certificate.

Patient Education - Atorvastatin 20 Mg Tablet

CONSUMER INFORMATION USE AND DISCLAIMER This generalized information is a limited summary of diagnosis, treatment, and/or medication information; It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

Atorvastatin
PRONUNCIATION (a TORE va sta tin)

BRAND NAME(S): Atorvaliq, and Lipitor

WHAT IS THIS DRUG USED FOR? It is used to lower bad cholesterol, lower triglycerides, and raise good cholesterol (HDL).; It is used in some people to lower the chance of heart attack, stroke, and certain heart procedures.; It is used to slow the progress of heart disease.; It may be given to you for other reasons. Talk with the doctor.

WHAT DO I NEED TO TELL MY DOCTOR BEFORE I TAKE THIS DRUG? If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.; If you have liver disease or raised liver enzymes.; If you are taking any of these drugs: Cyclosporine, gemfibrozil, gleaprevir plus pibrentasvir, letermovir, or tipranavir plus ritonavir.; If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.; If you are breast-feeding. Do not breast-feed while you take this drug.This is not a list of all drugs or health problems that interact with this drug.Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

WHAT ARE SOME THINGS I NEED TO KNOW OR DO WHILE I TAKE THIS DRUG? Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.; If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.; Have blood work checked as you have been told by the doctor. Talk with the doctor.; Follow the diet and workout plan that your doctor told you about.; If you drink grapefruit juice or eat grapefruit often, talk with your doctor.; Avoid or limit drinking alcohol to 2 drinks a day. Drinking too much alcohol may raise your chance of liver disease.; This drug may cause muscle pain, tenderness, or weakness. Sometimes, this may be severe and lead to kidney problems. Rarely, deaths have happened. The risk may be raised if you have thyroid problems, kidney problems, infection, or seizures. It may also be raised if you take certain other drugs or are dehydrated. People who are 65 or older may have a raised risk. Talk with your doctor if you have questions.; If you are 65 or older, use this drug with care. You could have more side effects.; This drug may cause harm to an unborn baby. If you may become pregnant, you must use birth control while taking this drug. If you get pregnant, call your doctor right away.

WHAT ARE SOME SIDE EFFECTS THAT I NEED TO CALL MY DOCTOR ABOUT RIGHT AWAY? WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect: Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.; Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.; Signs of a very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.; Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.; Not able to pass urine or change in how much urine is passed.; Feeling very tired or weak.; Feeling confused.; Memory problems or loss.; Call your doctor if you have muscle problems like abnormal muscle pain, tenderness, or weakness (with or without fever). If your doctor tells you to stop this drug but your muscle problems do not go away, call your doctor.; Severe and sometimes deadly liver problems have happened with this drug. Call your doctor right away if you have signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

WHAT ARE SOME OTHER SIDE EFFECTS OF THIS DRUG? All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away: Diarrhea.; Joint pain.; Pain in arms or legs.; Upset stomach.; Nose or throat irritation.; Signs of a common cold.; Trouble sleeping.These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

HOW IS THIS DRUG BEST TAKEN? Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.All products: Take this drug at the same time of day.; Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.Tablets: Take with or without food.Suspension: Take on an empty stomach. Take 1 hour before or 2 hours after meals.; Shake well before use.; Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

WHAT DO I DO IF I MISS A DOSE? Take a missed dose as soon as you think about it and go back to your normal time.; If it has been 12 hours or more since the missed dose, skip the missed dose and go back to your normal time.; Do not take 2 doses at the same time or extra doses.

HOW DO I STORE AND/OR THROW OUT THIS DRUG? Tablets: Store at room temperature in a dry place. Do not store in a bathroom.Suspension: Store in the original container at room temperature.; After opening, throw away any part not used after 60 days.All products: Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.; Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

GENERAL DRUG FACTS If your symptoms or health problems do not get better or if they become worse, call your doctor.; Do not share your drugs with others and do not take anyone else's drugs.; Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.; If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

DATE: 6/20/24

Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

RARE SPECIALTY PHARMACY
398 WEST GRAND AVENUE
RAHWAY, NJ 07065
(908) 296-2420

0010000 05/29/2024 Dr. Doctor Test
TEST PATIENT

TAKE ONE TABLET BY MOUTH DAILY

ATORVASTATIN 20 MG TABLET Qty 30
Use By: 02/25/2025
Generic for Lipitor
NO REFILLS
Mfg. Tev Rph: TEST PHARMACIST

EZ OPEN CASH

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Masum Amin

INITIALS: MA

PRINT NAME: Masum Amin

LICENSE/REGISTRATION #: 28RI03560800

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Monroe, NJ 08831

TELEPHONE NUMBER: [redacted]

EMAIL: [redacted]

DATE OF BIRTH: [redacted]

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 4/24/24

JOB DESCRIPTION: PIC

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

DATE: 6/20/2024

Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

RARE SPECIALTY PHARMACY
398 WEST GRAND AVENUE (908) 296-2420
RAHWAY, NJ 07065
00010002 06/10/2024 Dr. Doctor Test
TEST PATIENT

TAKE ONE TABLET BY MOUTH DAILY

AMLODIPINE BESYLATE 5 MG TAB Qty 30
Use By: 06/10/2025
Generic for Norvasc
REFILL (01) TIME AT 30 UNTIL 06/10/2025
Mfg:Tev Rph: TEST PHARMACIST EZ OPEN CASH

Owner

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: H.A. Herrera.

INITIALS: HAH

PRINT NAME: HECTOR A. HERRERA

LICENSE/REGISTRATION #:

HOME ADDRESS: [redacted]

CITY, STATE, ZIP SOMERVILLE, NJ 08876

TELEPHONE NUMBER: [redacted]

EMAIL: [redacted]

DATE OF BIRTH: [redacted]

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 4/26/24

JOB DESCRIPTION:

1701

RARE SPECIALTY PHARMACY

Room Temperature Log

Building: _____ Room: _____ Month_____

Date	Min Temp	Max Temp	AM Temp	Initials	PM Temp	Initials	Notes/Corrections Made

RARE
SPECIALTY PHARMACY

Refrigerator Temperature Log

Building: _____ Room: _____ Month_____

Date	Min Temp	Max Temp	AM Temp	Initials	PM Temp	Initials	Notes/Corrections Made

RARE SPECIALTY PHARMACY

Freezer Temperature Log

Building: _____ Room: _____ Month_____

Date	Min Temp	Max Temp	AM Temp	Initials	PM Temp	Initials	Notes/Corrections Made

RARE SPECIALTY PHARMACY

Policy Title: Inventory Management Policy

POLICY

Inventory shall be stored in accordance with all state and federal regulations as well as manufacturer recommendations in a secure facility that is clean, well-lighted and appropriate for the products that are being held for distribution by the pharmacy. Inventory shall be physically organized and separated by clear boundaries.

PROCEDURE

1. Purchasing and monitoring of inventory
    A. The pharmacy ensures stability of inventory by only purchasing from licensed wholesalers, licensed distribution channels or drug manufacturers in accordance with state and federal regulations, including the Drug Chain Security Act (DCSA, Title II of the Drug Quality and Security Act of 2013).
    B. Upon receipt of medications the pharmacy monitors for unacceptable medications, including counterfeit drugs. Each product is inspected for color, shape, consistency, and evidence of modification to packaging. In the event of a suspicious drug product, the distributor will be contacted directly by pharmacy leadership to initiate the investigation, and the product placed in the pharmacy quarantine area until deemed to be acceptable for incorporation into pharmacy stock.
    C. Continuously, the pharmacy addresses out of stock and backorder products to ensure supply to patients is not interrupted. Patients will be notified if such a delay is expected. The organization addresses the issue by the following:
        i. Alternative suppliers
        ii. Transfer to alternative pharmacy
        iii. Contact prescriber to find alternate product
    D. Inventory is managed by the pharmacy daily using:
        i. Stock rotation
        ii. Cycle counts
        iii. Expiration date checks
    E. Continuous, 24-hour electronic monitoring is in place for all drug storage areas to maintain the following appropriate temperature ranges as defined by the recommendation of USP <659>:
        i. Refrigerators storing medications (food refrigerators must be labeled appropriately and designated for food only): 36 to 46°F
        ii. Freezers (all freezers regardless of drug storage, including freezers for ice packs): -13 to 14°F
        iii. Ambient room air temperature: 68 to 77°F
        iv. Humidity: Average relative humidity is less than 40%
    F. In the event of a temperature excursion, the pharmacist will identify a list of affected medications and review the appropriate manufacturer guidelines or other published literature to determine if the excursion was acceptable. Until the pharmacist review is complete, these medications will be quarantined. If the breakdown exceeds manufacturer recommendations, then the medication will remain quarantined until returned to the distributer for appropriate destruction. In the event of a temperature excursion from the manufacturer's specifications lasting 24 hours or more, the pharmacist in charge will notify the Board of Pharmacy immediately. Notification shall be made in that the notice is received by the Board of Pharmacy within 48 hours of becoming aware of the temperature excursion.
    G. Currently, the pharmacy does not participate in inventory storage thermal mapping.

H. A list of drugs and routes not approved for administration by nursing personnel are maintained in the pharmacy and reviewed/approved annually by the Quality Management Committee.

2. Medication Returns
   A. Generally, after a medication leaves the pharmacy for delivery to a patient it may not be returned to pharmacy stock due to the absence of continuous temperature monitoring and concern for patient safety. However, if a package is delivered by courier or contains specific continuous temperature surveillance (documentation of a high and low temperature) for the entire time the package is away from the pharmacy and is never signed out to a patient, pharmacy leadership may review records and determine if the return is safe and acceptable.
   B. If the medication has been given to the patient it may not be returned to pharmacy stock in accordance with state and federal regulations.
   C. All patient medication disposal must be conducted through appropriate legal channels such as drug take back days or designated drug disposal stations in accordance with state and federal law. The pharmacy may not accept medications from a patient for the purpose of disposal.

3. Quarantine and Disposal
   A. Unacceptable medications include recalled, discontinued, expired, damaged, adulterated, misbranded or counterfeit.
   B. When a notification is received regarding an unacceptable medication, information will be recorded, and education will be provided to staff, patients, and prescribers as necessary and based on direction from manufacturers and regulators. Receipt of notifications may come from patients, manufacturers, FDA, etc.
      i. Current inventory will be reviewed, and unacceptable medication removed.
      ii. Inventory in the shipping process will be reviewed to identify medication that requires removal.
   C. Unacceptable medication will be quarantined and disposed of according to state and federal law via the original distributor or a reverse distributor. If necessary, patients will be counselled by a pharmacist on the correct method of drug disposal.

4. Manufacturer and FDA Requirements
   A. When a new medication is added to the pharmacy formulary, pharmacy leadership and clinical staff will review and implement FDA guidance and all self-imposed manufacturer requirements, including REMS requirements. All team members will be educated regarding the specifics of each requirement, and where to find more information regarding the requirement (e.g. the FDA website). All new medications and new requirements to current medications will be reviewed and approved by the Quality Management Committee for implementation to promote ongoing compliance.
   B. Annually, the list of medications with FDA or manufacturer requirements will be reviewed and approved by the Quality Management Committee.
   C. In the event of a new FDA guidance or self-imposed manufacturer restriction that may cause a potential safety event (new black box warning, new REMS program, additional adverse drug events), the pharmacy will print a list of active patients receiving the applicable medication and notify the patient/caregiver and prescriber, as is most appropriate for the situation.

5. Equipment and supplies
    A. Equipment, supplies and devices will be purchased from legitimate sources, stored appropriately, and removed from active stock if adulterated.
    B. Procedures will be written, stored on file and employees educated for any equipment or supplies available for dispense in the pharmacy. Procedures will include:
        i. Storage and transportation of equipment used to provide care/services
        ii. Electrical safety of the equipment
        iii. Use of cleaning and disinfecting agents
        iv. Cleaning of equipment after each use
        v. Maintenance and repair of equipment used by the organization's personnel
        vi. Calibration per manufacturer's guidelines, if applicable
        vii. Requirements for dispensing of any disposable supply used in the provision of care/service
        viii. Manufacturer's recalls

6. Wholesale Distribution
    A. Drugs purchased under the pharmacy licensed are never transferred to a wholesale distribution license.

RELATED PROCESS DOCUMENTS

NEW JERSEY DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES

CERTIFICATE OF FORMATION

RARE SPECIALTY SERVICES LLC
0451119765

The above-named DOMESTIC LIMITED LIABILITY COMPANY was duly filed in accordance with New Jersey State Law on 04/26/2024 and was assigned identification number 0451119765. Following are the articles that constitute its original certificate.

1. **Name:**
   RARE SPECIALTY SERVICES LLC
2. **Registered Agent:**
   HECTOR HERRERA
3. **Registered Office:**
   398 W GRAND AVENUE
   RAHWAY, NEW JERSEY 07065
4. **Business Purpose:**
   SPECIALTY SERVICES INCLUDING PHARMACY
5. **Effective Date of this Filing is:**
   04/26/2024
6. **Members/Managers:**
   CASH&J
   114 W CLIFF STREET
   SOMERVILLE, NEW JERSEY 08876
7. **Main Business Address:**
   398 W GRAND AVENUE
   RAHWAY, NEW JERSEY 07065

Signatures:

HECTOR HERRERA
AUTHORIZED REPRESENTATIVE

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal 26th day of April, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 4241855501
Verify this certificate online at
https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Case # 8-7283-24-679
Exhibit #12
Page 1 of 1

STATE OF NEW JERSEY
BUSINESS REGISTRATION CERTIFICATE

Taxpayer Name:	RARE SPECIALTY SERVICES LLC
Trade Name:	
Address:	398 W GRAND AVENUE RAHWAY, NJ 07065
Certificate Number:	2980443
Effective Date:	April 29, 2024
Date of Issuance:	May 16, 2024

For Office Use Only:

20240516131308941

NEW JERSEY DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
CERTIFICATE OF ALTERNATE NAME

RARE SPECIALTY SERVICES LLC
0451119765

I, the Treasurer of the State of New Jersey, do hereby certify that the above-name did on the 28th of May, 2024, file and record in this department a Certificate of Alternate Name.

1. Business Name: RARE SPECIALTY SERVICES LLC

2. New Jersey Business Entity ID: 0451119765

3. Alternate Name:

Name: RARE SPECIALTY PHARMACY

Activity To Be Conducted Using Alternate Name
SPECIALTY PHARMACY

Alternate Name is Valid Until: 05/28/2029

Signature and Title

HECTOR HERRERA, CHIEF OPERATION OFFICER

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 28th day of May, 2024

Elizabeth M. Muoio
State Treasurer

Certificate Number : 4244898856

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

RARE
SPECIALTY PHARMACY

June 20, 2024

Domenica (Donna) Kapetanakis, PharmD, Investigator
Office of the Attorney General Dpt of Law & Public Safety
Division of Consumer Affairs
Enforecement Bureau
P.O. Box 45022
Newark, NJ 07101

Dear Donna,

As a follow-up from the on-site inspection on 06.20.24, all PHi will be stored within the 398 specialty pharmacy area only.

Thank you,

Hector A. Herrera
Chief Executive Officer

Masum Amin, PharmD, CSP
Pharmacist in Charge

OMAR TORRES
Commission # 50185892
Notary Public, State of New Jersey
My Commission Expires
February 16, 2027

RARE
SPECIALTY PHARMACY

August 15, 2024

Domenica (Donna) Kapetanakis, PharmD, Investigator
Office of the Attorney General Dpt of Law & Public Safety
Division of Consumer Affairs
Enforecement Bureau
P.O. Box 45022
Newark, NJ 07101

Dear Donna,

As a follow-up from the on-site inspection on 06.20.24, Rare Specialty Pharmacy is an open door pharmacy, focusing on rare and advanced disease states. Rare will obtain the NJ home state permit and has plans to expand nationally in all 50 states plus Washington D.C., while getting accredited as a specialty pharmacy through URAC and ACHC. The Pharmacy will not have a central fill agreement and will hand deliver all prescriptions in NJ. Rare Specialty Pharmacy will not engage in any specific physician office or telehealth platform agreement nor have any shared services with any other pharmacies in any states.

Thank you,

Hector A. Herrera
Chief Executive Officer

Masum Amin, PharmD, CSP
Pharmacist in Charge

AGATHA PEREZ
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50187704
MY COMMISSION EXPIRES MAR. 08, 2027

8/15/24

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Stellar Pharmacy Services, Inc. dba Stellar Rx

Physical Address: 302 Industrial Drive

City: Avondale State: PA Zip: 19311

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 610.910.9580 Toll Free # (NAC 639.708, NRS 639.23286): 800.910.2959

Fax: 610.537.5055 Contact Email: tony@stlrrx.com

Website: www.stlrrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Anthony P. Cappello RPh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24505

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Anthony P. Cappello (PA License RP031494L)	NV Pharmacist Registration #: 24505
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): —/—

Corporation/Organization Name: Stellar Pharmacy Services, Inc.

Mailing Address: 302 Industrial Drive

City: Avondale State: PA Zip: 19311

Telephone: 610.910.9580 Email: heather@stlrrx.com

Contact Person Name: Heather Ruszin

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/CEO (title) ~~for~~ Stellar Pharmacy Services Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Heather Ruszin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/5/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Anthony P Cappello hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager (title) for Stellar Pharmacy Services, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 16th day of November, 2024

Notary Public

Commonwealth of Pennsylvania - Notary Seal
Joseph Johnson, Notary Public
Chester County
My commission expires November 16, 2025
Commission number 1219801
Member, Pennsylvania Association of Notaries

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Heather Ruszin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/05/2024

Date

Board Use Only	Date Received: 11/27/24	Amount: $500 ck 1103

Ownership, Officers & Pharmacist Information for Stellar Pharmacy Services, Inc.

- Business Corporation for Profit
- Professional Corporation "S Corporation"
- Date of Incorporation in PA: 9-4-2014 Entity#: 4293908

1. Heather A. (Ann) Ruszin (maiden name: [redacted])

[redacted]

Corporate position/Title: President/CEO
Home address [redacted] West Grove, PA [redacted]

[redacted]

Work Phone #: 610-910-9580 ext. 1020
Fax #: 610-537-5055
Email: heather@stlrrx.com
% of ownership = 33.3%

[redacted]

2. Mark George Steltz (uses Mark G. Steltz on legal documents)

[redacted]

PA Pharmacist License#: RP037693L (initial license date: 8/11/1990) exp. 9/30/2024
Personal NPI#: N/A (does not have one)
Corporate position/Title: Vice President/CFO (Chief Financial Officer)
Home address: [redacted] Glen Mills, PA [redacted]

[redacted]

Work Phone #: 610-910-9580 ext. 1025
Fax #: 610-537-5055
Email: mark@stlrrx.com
% of Ownership = 33.3%

[redacted]

Freedom Pharmacy
3605 Edgmont Ave
Bldg B
Brookhaven, PA 19015
Phone #: 855-539-7865
Fax #: 866-250-1718

- PA Pharmacy License #: PP481827 (initial issue date: 5-6-2008) exp. 8/31/2025
- NCPDP# 6002377
- Tax ID# 47-3059847

- NPI# 1942687116
- Does not bill Medicare or Medicaid
- Owns 22.5%

3. Brian E. Steltz
[redacted]

PA Pharmacist License #: RP040820L (initial license date: 3/2/1995) exp. 9/30/2024
PA Immunizing Pharmacist License #: RPI003040 exp. 9-30-2024
DE Pharmacist License #: A1-0003014 (initial license date: 5-27-1999) exp. 9/30/2024
NJ Pharmacist License #: 28RI02654200 (initial license date: 1-27-1999) exp. 4/30/2025

Personal NPI #: [redacted]
Corporate position/Title: Co-owner (6/1/2014 – Present) and COO (6/1/2014 – 1/6/2023)
Home address: [redacted] Malvern, PA [redacted]
[redacted]
% of Ownership = 33.3%
[redacted] (County: Columbia)

Stellar business practice location address: 302 Industrial Drive, Avondale, PA 19311
Phone #: 484-213-4888
Fax #: 610-537-5055
Email: brian@stlrrx.com

Consolidated Medical Supply (DME)
Consolidated Rx (Pharmacy)
23 W. Industrial Blvd
Paoli, PA 19301
Office #: 610-578-0411
Fax #: 610-578-0419
Email: brian@cmedsupply.com
Ownership: 100%
PA Pharmacy License# PP482947
Tax ID: 23-3058164
NCPDP #: 3978535
NPI #: 1144275769

4. Melissa Jane Broscious (maiden name: [redacted])
[redacted]

Corporate position/Title: COO (Chief Operating Officer) as of 1/9/2023
Home address: [redacted], Harrisburg, PA [redacted]
[redacted]
Work Phone #: 610-910-9580 ext. 1026
Fax #: 855-368-8031
Email: melissa@stlrrx.com
% of Ownership: 0.00%
[redacted]

5. Anthony Cappello
[redacted]
PA Pharmacist License #: RP031494L (exp. 9/30/2024)
TN Pharmacist License #: 47059 (exp. 6/30/2025)
MS Pharmacist License #: T-101155 (exp. 12/31/2024)
NJ Pharmacist License #: 28RI02516000 (exp. 4/30/2025)
Personal NPI #: [redacted]
Corporate position/Title: Pharmacy Manager & Wholesale Manager
Home address: [redacted] West Chester, PA [redacted]
[redacted]
Fax #: 610-537-5055
Work Phone #: 610-910-9580 ext. 1164
Email (work): tony@stlrrx.com
Email (other): apcapello@yahoo.com
% of Ownership: 0.00%
[redacted]

6. Maureen Lupoli
[redacted]
PA Pharmacist License #: RP032750L (exp. 9/30/24)
Personal NPI #: N/A
Corporate position/Title: Pharmacist
Home address: [redacted] Garnet Valley, PA [redacted]
[redacted]
Fax #: 610-537-5055
Work Phone #: 610-910-9580 ext. 1040
Email (work): maureen@stlrrx.com
% of Ownership: 0.00%
[redacted]

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	STELLAR PHARMACY SERVICES, INC.		
Request Type:	Subsistence Certificate	**Issuance Date:**	November 20, 2024
Request No.:	046497541	**File No.:**	0004293908
Receipt No.:	001306573		
Filing Type:	Domestic Business Corporation		
Filing Subtype:	Business		
Initial Filing Date:	September 04, 2014		
Status:	Active		

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

STELLAR PHARMACY SERVICES, INC.

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stellar Pharmacy Services, Inc dba Stellar Rx

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 302 Industrial Dr

City: Avondale State: PA Zip: 19311

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 610.910.9580 Website: www.stlrrx.com

Licensing Company Email: tony@stlrrx.com

Section 2: Personal Information

First: Anthony Middle: Patrick Last: Cappello

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: West Chester State: PA Zip: [redacted]

Telephone: _____ Email: _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy and Science		09/75-12/80	
Address	**City**	**State**	**Zip**
Kingsessing Ave and 42nd St	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
BSc/Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Msgr Bonner High School		09/71-05/75	
Address	**City**	**State**	**Zip**
Garrett Rd	Drexel Hill	PA	19026
Diploma/Degree obtained, if any			
General			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/11-Present	[redacted]	West Chester	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Stellar Health Services, Inc dba Stellar Rx			12/20-Present	
Business Address	**City**		**State**	**Zip**
302 Industrial Dr	Avondale		PA	19311
Phone	**Title**		**Number of Employed Hours**	
610.910.9580	Staff Pharmacist/Pharmacy Manager		3000	
Description of Duties				
Dispensing pharmacist/Pharmacist Manager, dispensing as well as regulatory affairs				

Business Name			From - To (MM/YY – MM/YY)	
Giant Food Pharmacy #6045			11/06-06/23	
Business Address	**City**		**State**	**Zip**
841 W Baltimore Pk	West Grove		PA	19390
Phone	**Title**		**Number of Employed Hours**	
610.345.1426	Pharmacy Manager		33000	
Description of Duties				
Dispensing pharmacist, regulatory affairs, staff manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Anthony P. Cappello, **certify that as the designated representative for**

Stellar Pharmacy Services, Inc. dba Stellar Rx,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Anthony Cappello

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony Cappello

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, Anthony P Cappello, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/2024

Date

Subscribed and Sworn to before me this 20 day of November, 24

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Perla Ocampo Davalos, Notary Public
Chester County
My commission expires March 28, 2026
Commission number 1499146
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Stellar Pharmacy Services, Inc. dba Stellar RX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP482529

Physical Address: 302 Industrial Drive

City: Avondale State: PA Zip: 19311

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 610.910.9580 Website: www.stlrrx.com

Licensing Company Email: heather@stlrrx.com

Section 2: Personal Information

First: Heather Middle: Ann Last: Ruszin

Alias(es, nick[redacted]nges, etc.): Heather Ann Murray (maiden name)

Date of Birth: [redacted] SSN or ITI[redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: West Grove State: PA Zip: [redacted]

Telephone: [redacted] Email: heather@stlrrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
DCCC		9/93 to 6/96	
Address	**City**	**State**	**Zip**
901 Media Line Road	Media	PA	19063
Diploma/Degree obtained, if any			
Associated Degree			

School Name		From - To (MM/YY – MM/YY)	
Archbishop Prendergast High School		9/89 to 6/93	
Address	**City**	**State**	**Zip**
403 North Lansdowne Ave	Drexel Hill	PA	19026
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/05 to current	[redacted]	West Grove	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Stellar Pharmacy Services, Inc			10/14 to current	
Business Address		**City**	**State**	**Zip**
302 Industrial Drive		Avondale	PA	19311
Phone	**Title**			
610-910-9580	Co-Owner			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Stellar Health Services, LLC			3/18 to current	
Business Address		**City**	**State**	**Zip**
301 Industrial Drive		Avondale	PA	19311
Phone	**Title**			
610-276-5823	Co-Owner			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Aspire Product Solutions, LLC			3/19 to Current	
Business Address		**City**	**State**	**Zip**
201 B Industrial Drive		Avondale	PA	19311
Phone	**Title**			
610-806-2603	Co-Owner			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Heather Ruszin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 11/13/2024

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, Heather A. Ruszin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 11/13/2024

Subscribed and Sworn to before me this 13 day of November.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Perla Ocampo Davalos, Notary Public
Chester County
My commission expires March 28, 2028 (Seal)
Commission number 1409146
Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Stellar Pharmacy Services, Inc. dba Stellar RX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP482529

Physical Address: 302 Industrial Drive

City: Avondale State: PA Zip: 19311

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 610-910-9580 Website: www.stlrrx.com

Licensing Company Email: heather@stlrrx.com

Section 2: Personal Information

First: Brian Middle: E Last: Steltz

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City: Malvern State: PA Zip: [redacted]

Telephone: [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Philadelphia College of Pharmacy and Science		09/1989 - 05/1994	
Address	**City**	**State**	**Zip**
S 43rd St & Woodland Ave	Philaadelphia	PA	19104
Diploma/Degree obtained, if any			
Bachelor of Science Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
US Army Academy of Health Sciences		8/1987 - 03/1989	
Address	**City**	**State**	**Zip**
Fort Sam Houston	San Antonio	TX	78234
Diploma/Degree obtained, if any			
91A/91Q			

School Name		From - To (MM/YY – MM/YY)	
Danville Area High School		09/1983 - 05/1987	
Address	**City**	**State**	**Zip**
600 Walnut St	Danville	PA	17821
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2017- Present	[redacted]	Malvern	PA	
12/1996 - 10/2017		King of Prussia	PA	
12/2006 - Present		North Cape May	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Stellar Pharmacy Services, Inc. dba Stellar RX		12/2014 - Present	
Business Address	**City**	**State**	**Zip**
302 Industrial Drive	Avondale	PA	19311
Phone	**Title**		
610-910-9580	No Title/NA		
Description of Duties			
Co-Owner/No Job Duties			

Business Name		From - To (MM/YY – MM/YY)	
Steltz Pharmacy, Inc dba Consolidated Medical Supply		09/2000 - Present	
Business Address	**City**	**State**	**Zip**
23 W Industrial Blvd	Paoli	PA	19301
Phone	**Title**		
610-578-0419	President/CEO		
Description of Duties			
Managing/overseeing current operations and directing future growth.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	N/A		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	N/A		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	N/A		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian E Steltz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, Brian E Steltz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/24

Date

Subscribed and Sworn to before me this 19 day of Nov 2024.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Mary M. Meindl, Notary Public
Delaware County
My commission expires April 7, 2027
Commission number 1109809
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Stellar Pharmacy Services, Inc. dba Stellar RX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP482529

Physical Address: 302 Industrial Drive

City: Avondale State: PA Zip: 19311

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 610.910.9580 Website: www.stlrrx.com

Licensing Company Email: heather@stlrrx.com

Section 2: Personal Information

First: Mark Middle: George Last: Steltz

Alias(es, nicknames, previous names, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Glen Mills State: PA Zip: [redacted]

Telephone: [redacted] Email: mark@stlrrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Drexel University		1993 - 1999	
Address: 3141 Chestnut St	City: Phila	State: PA	Zip: 19104
Diploma/Degree obtained, if any: Master in Business MBA			
School Name: University of the Sciences (now St Joseph's)		From - To (MM/YY – MM/YY): 9/1985-5/1990	
Address: 600 S 43rd St	City: Phila	State: PA	Zip: 19104
Diploma/Degree obtained, if any: BS in Pharmacy			
School Name: Danville high School		From - To (MM/YY – MM/YY): 8/1981-5/1985	
Address: 600 walnut St	City: Danville	State: PA	Zip: 17821
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2004 - Curr	[redacted]	Glen Mills	PA	[redacted]
1/2009 - Curren		Ocean City	NJ	
8/2020 - Curren		Marco Island	FL	
9/2008 - 9/20		ocean city	nj	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: PharmPro Staffing			From - To (MM/YY – MM/YY): 2/2002 / present	
Business Address: 3605 Edgemont Ave	City: Brookhaven		State: PA	Zip: 19015
Phone: 610-499-9040	Title: President			
Description of Duties: Direct Pharmacy Staffing Business				

Business Name: M+K Associates			From - To (MM/YY – MM/YY): 10/2010 – present	
Business Address: 3605 Edgemont Ave	City: Brookhaven		State: PA	Zip: 19015
Phone: 610-276-5830	Title: Vice President			
Description of Duties: Keep Books - Building Maintenance decisions				

Business Name: Freedom Pharmacy			From - To (MM/YY – MM/YY): 5/2015 – present	
Business Address: 3605 Edgemont Ave Suite B	City: Brookhaven		State: PA	Zip: 19015
Phone: 610-274-5830	Title: CFO - VP opps			
Description of Duties: Keep Book -> help Strategic Plan				

Business Name: Stellar Pharmacy Services			From - To (MM/YY – MM/YY): 10-2017 – present	
Business Address: 302 Industrial Dr	City: Audubon		State: PA	Zip: 19311
Phone: 610-910-9580	Title: CFO			
Description of Duties: Financial + Fiscal Planning				

Business Name: Stellar Health Services			From - To (MM/YY – MM/YY): 2018 – present	
Business Address: 302 Industrial Pl	City: Audubon		State: PA	Zip: 19311
Phone: 610-910-9580	Title: CFO			
Description of Duties: Financial + fiscal Planning				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Steltz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, MARK George Steltz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2024

Date

Subscribed and Sworn to before me this 19th day of November 2024

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Rosa M. Ramos Cabrera, Notary Public
Chester County
My commission expires June 4, 2025
Commission number 1311578
Member, Pennsylvania Association of Notaries

(Seal)

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

STELLAR RX

302 INDUSTRIAL DR
Avondale, Pennsylvania, 19311

Phone: 610-910-9580
Owner: STELLAR PHARMACY SERVICES INC.

LICENSE

License No: PP482529
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 09/06/2024
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

STELLAR RX

302 INDUSTRIAL DR
Avondale, Pennsylvania, 19311

Phone: 610-910-9580
Owner: STELLAR PHARMACY SERVICES INC.

LICENSE

License No: PP482529
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 09/06/2024
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

ROBERT MONTGOMERY	9/6/2024 12:25:32 PM	Maureen Lupoli - RP032750L
Signature of Inspector	Date/Time	Signature of Owner/Representative

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

07/16/2024

License Information

STELLAR RX

302 INDUSTRIAL DR
Avondale, Pennsylvania 19311

Board/Commission:	State Board of Pharmacy	Status Effective Date:	12/02/2014
LicenseType:	Pharmacy	Issue Date:	12/02/2014
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2025
License Number:	PP482529	Last Renewal:	07/13/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ANTHONY PATRICK CAPPELLO	Pharmacist Manager	Pharmacist	RP031494L	Active	06/27/2024	09/30/2024

Disciplinary Action Details

No disciplinary actions were found for this license.

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

COPY

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

23 0056531

License Type
Pharmacy

STELLAR RX
MARIA LYNNE TAYLOR
302 INDUSTRIAL DR
AVONDALE, PA 19311

License Status
Active

Initial License Date
12/02/2014

COPY

Expiration Date
08/31/2025

License Number
PP482529

COPY

Acting Commissioner Arion R. Claggett

Signature

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

03/13/2025

License Information

STELLAR RX

302 INDUSTRIAL DR
Avondale, Pennsylvania 19311

Board/Commission:	State Board of Pharmacy	Status Effective Date:	12/02/2014
LicenseType:	Pharmacy	Issue Date:	12/02/2014
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2025
License Number:	PP482529	Last Renewal:	07/13/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ANTHONY PATRICK CAPPELLO	Pharmacist Manager	Pharmacist	RP031494L	Active	06/27/2024	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

11/05/2024

License Information

STELLAR RX

302 INDUSTRIAL DR
Avondale, Pennsylvania 19311

Board/Commission:	State Board of Pharmacy	Status Effective Date:	12/02/2014
LicenseType:	Pharmacy	Issue Date:	12/02/2014
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2025
License Number:	PP482529	Last Renewal:	07/13/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ANTHONY PATRICK CAPPELLO	Pharmacist Manager	Pharmacist	RP031494L	Active	06/27/2024	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS4975263	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-23-2024

STELLAR RX
STELLAR PHARMACY SERVICES, INC.
302 INDUSTRIAL DR
AVONDALE, PA 193119769

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS4975263	02-28-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-23-2024

STELLAR RX
STELLAR PHARMACY SERVICES, INC.
302 INDUSTRIAL DR
AVONDALE, PA 193119769

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Received 7/1/24

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Long term, closed door, medication management pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Long term, med mgmt

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: SelectRx KS, LLC

Physical Address: 418 W. Frontier Lane

City: Olathe State: Kansas Zip: 66061-7221

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-705-6810 Toll Free # (NAC 639.708, NRS 639.23286): 888-705-6810

Fax: 317-913-0930 Contact Email: Qi.Compliance@selectrx.com

Website: www.selectrx.com

Nevada Business License # (if applicable) NV20243167576

Supervising/Managing Pharmacist Name (NRS 639.220): Whittney. D Steele

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24331

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Whittney D. Steele	NV Pharmacist Registration #: 24331
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): SelectQuote Ventures, Inc

Corporation/Organization Name: SelectRX KS, LLC

Mailing Address: 418 W. Frontier Lane

City: Olathe State: Kansas Zip: 66061-7221

Telephone: 888-705-6810 Email: QI.Compliance@selectrx.com

Contact Person Name: Whittney D. Steele

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Secretary (title) for SelectRx KS, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Daniel A. Boulware

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

01/08/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Daniel A. Boulware hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary (title) for SelectRx KS, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of January, 2025

Notary Public Erin Leigh Anderson

STATE OF KANSAS
COUNTY OF JOHNSON

My Commission Expires: 03/21/2026

ERIN LEIGH ANDERSON
Notary Public - State of Kansas
My Appointment Expires 3/21/26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel A. Boulware, Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

01/08/2025

Date

Board Use Only	Date Received: 2/18/25	Amount: $500 - ck 60841

SelectRx KS, LLC

Owner and Officer Details

Parent Entity: 100% Owner
SelectQuote Ventures, Inc.
6800 W 115th Street, Suite 2511 Overland Park, KS 66211
TEL: 913-599-9225
Tax ID – 86-2734618

Corporate Officers: 0% Owner/Stock

Robert Grant, President
6800 W. 115th St, Ste 2511 Overland Park, KS 66211

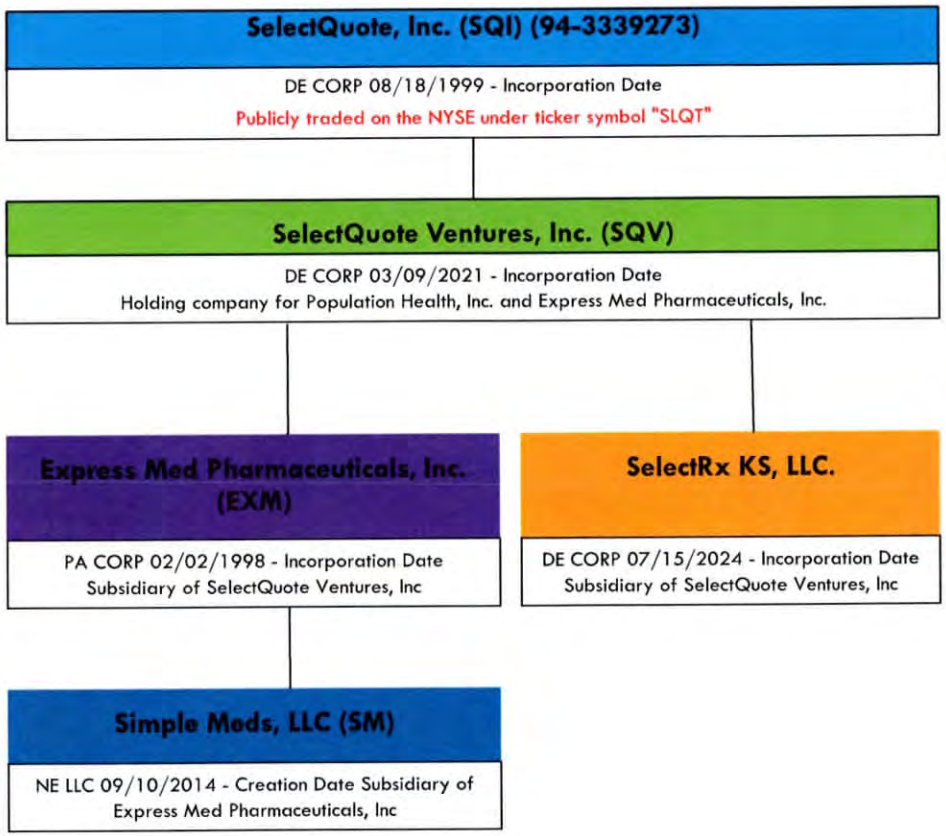
Ryan M. Clement, Treasurer
6800 W. 115th St, Ste 2511 Overland Park, KS 66211

Daniel A. Boulware, Secretary
6800 W. 115th St, Ste 2511 Overland Park, KS 66211

Stephanie Fisher, Asst Treasurer
6800 W. 115th St, Ste 2511 Overland Park, KS 66211

SelectRx

ORGANIZATION CHART



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF REGISTRATION
FOREIGN LIMITED-LIABILITY COMPANY

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **SelectRx KS, LLC** did on 07/25/2024 file in this office its registration to do business in this state and is now on file and of record in the office of the Nevada Secretary of State, and further, that said entity is at the date of this certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/25/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202407254829873
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

SelectRx KS, LLC

Nevada Business Identification # NV20243167576
Expiration Date: 07/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/25/2024.

Certificate Number: B202407254829874
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SelectRx KS, LLC
Physical Address 418 W Frontier Lane
City Olathe State KS Zip 66061-7221
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 888-705-6810 Website www.selectrx.com
Licensing Company Email Qi.Compliance@selectrx.com

Section 2: Personal Information

First Whittney Middle D. Last Steele
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X
Mailing Address [redacted]
City Prairie Village State KS Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____
Military Occupation/Specialty _____
Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Applicant's initials WS

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Kansas School of Pharmacy			08/13-05/17	
Address		City	State	Zip
2010 Becker Dr		Lawrence	KS	66047
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Hutchinson Community College			08/10-05/13	
Address		City	State	Zip
1300 N Plum St		Hutchinson	KS	67501
Diploma/Degree obtained, if any				
Associate of Arts				
School Name			From - To (MM/YY – MM/YY)	
Buhler High School			08/06-05/10	
Address		City	State	Zip
611 N Main St		Buhler	KS	67522
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19-Present	[redacted]	Prairie Village	KS	[redacted]
09/17-5/19		Roeland Park	KS	
08/16-08/17		Kansas City	MO	
06/14-07/16		Lawrence	KS	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
SelectRx KS, LLC		06/10/2024 - Present	
Business Address	**City**	**State**	**Zip**
418 W. Frontier Lane	Olathe	KS	66061-7221
Phone	**Title**	**Number of Employed Hours**	
888-705-6810	Pharmacist in Charge	1400	
Description of Duties			
regulatory compliance, audits & inspection, quality assurance			

Business Name		From - To (MM/YY – MM/YY)	
Auburn LTC Pharmacy		04/2017 - 04/2024	
Business Address	**City**	**State**	**Zip**
401 W Frontier Ln.	Olathe	KS	66061
Phone	**Title**	**Number of Employed Hours**	
913-294-9125	Operations Manager	14,560	
Description of Duties			
oversaw operations in pharmacy, staff supervision, facility liason			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Applicant's initials WS

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Whittney D. Steele, **certify that as the designated representative for**

SelectRx KS, LLC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Whittney D. Steele

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/2025

Date

Applicant's initials WS

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Whittney D. Steele

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Kansas, ss. County of Johnson

I, Whittney Steele, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/29/2025

Date

Subscribed and Sworn to before me this 29 day of 01/29/2025 2025.

RHYS TAYLOR SHEPARD
Notary Public - State of Kansas
My Appointment Expires 10/20/26

Rhys Taylor Shepard

Notary Public Signature

(Seal)

Applicant's initials WS

Kansas Board of Pharmacy
800 SW Jackson St. Suite 1414
Topeka, Kansas 66612-1244
P:785-296-4056
F:-785-296-8420

INSPECTION REPORT FOR: 2-124646

SelectRx KS, LLC 418 W. Frontier Lane Olathe, KS 66061	Original Date: 1/31/2025 On Probation: No Discipline on File: No
INSPECTION REPORT	Inspection Date: 1/31/2025 Inspector: Melissa Martin

This inspection report is not intended as an exhaustive listing of all pharmacy conditions. There may be deficiencies, non-compliance, or violation(s) of Kansas laws or regulations not detected, observed, or noted in this report.

Inspection Key
C-Compliant | N/I-Needs Improvement | N/C-Not Compliant | U-Unassessed | N/A-Not Applicable
Asterisk * denotes Pharmacist in Charge responsibility

GENERAL INFORMATION	C	N/I	N/C	U	N/A
Pharmacy registration displayed—K.S.A. 65-1645(e)					X
DEA number: pending					X
Combat Meth Self-Certification—21 C.F.R. 1314.35 & 21 C.F.R. 1314.40					X
K-TRACS poster—K.A.R. 68-21-4(a)					X
Pharmacist license(s) posted—K.S.A. 65-1641					X
Pharmacist intern registration(s) posted—K.S.A. 65-1676(h)					X
Technician registration(s) posted—K.S.A. 65-1663(j)					X
All personnel registered or licensed—K.S.A. 65-1631 & K.S.A. 65-1663 *					X
Name tags—K.A.R. 68-2-15					X
Pharmacist(s) on duty:	Whittney				
Pharmacist in Charge:	Steele, Whittney Danielle				
Pharmacists:					
Interns:					
Technicians:					
General Information Notes: Completed pre-opening inspection of the pharmacy space. DEA # pending.					

PRACTICE SETTING	C	N/I	N/C	U	N/A
Specialty pharmacy:	Yes				
Type: Closed Door Mail Order Pharmacy					
Is the facility accredited by a national accreditation organization:					
If so, by whom:					
Participates in 340B:					
Qualifying 340B entity:					
Dispensing oxygen:					
Transfilled by:					
Facility compounds sterile product:	No				
If facility compounds sterile product:					
Facility compounds nonsterile products:	No				
If facility compounds nonsterile product:					
Practice Setting Notes: No compounding (non or sterile) medications					

FACILITIES	C	N/I	N/C	U	N/A
Pharmacy clean, well-lit, etc.—K.S.A. 65-1642(a) & K.S.A. 65-668(a) & K.S.A. 65-656(m)	X				
Drugs stored per manufacturer—K.S.A. 65-1634	X				
Outdated, mislabeled, or adulterated drugs have been removed from stock —K.S.A. 65-1634 & K.S.A. 65-657(a)					X

Reference material available—K.S.A. 65-1642 & K.A.R. 68-2-12a	X				
Access to current KS Pharmacy Laws/Regulations—K.S.A. 65-1642 & K.A.R. 68-2-12a	X				
Policy and procedures—K.A.R. 68-7-12(c) *	X				
Necessary equipment and supplies—K.S.A. 65-1642 & K.A.R. 68-2-12a	X				
Room temperature:	yes				
Refrigerator temperature:	multiple fridges				
Freezer temperature:	freezers for ice packs				
Facilities Notes: No medication in inventory. Pharmacy shell space only.					
SECURITY	**C**	**N/I**	**N/C**	**U**	**N/A**
Secure when pharmacist is not on duty—K.A.R. 68-2-11	X				
Prepackaging/Repackaging area secure when pharmacist is not in attendance in area—K.A.R. 68-7-15(e)					X
Keys only with pharmacist(s)—K.A.R. 68-2-11	X				
Controlled drugs locked or dispersed—21 C.F.R. 1301.75	X				
Security Notes: Will have CII's eventually in narcotic cage. Pharmacy is secure, alarmed and with cameras. Exterior perimeter lighting. Badge access only					
RECORDS	**C**	**N/I**	**N/C**	**U**	**N/A**
Documentation of staff training for Combat Meth Self-Certification—21 C.F.R. 1314.35					X
K-TRACS reporting—K.S.A. 65-1683					X
Initial notification and DEA 106 loss or theft reported to Board—K.A.R. 68-20-15b					X
Duration of record keeping—K.S.A. 65-1642(b)&(c)(3) & K.A.R. 68-20-16(a)					X
Central record keeping—21 C.F.R. 1304.04(b)(3)					X
Records readily retrievable—21 C.F.R. 1300.01(b)(38) & K.S.A 65-1626(iii) & 65-4101(oo)					X
Location:					
Records Notes: Applicant for Retail Closed Door Mail Order Pharmacy					
ELECTRONIC DATA STORAGE SYSTEMS—K.A.R. 68-9-1 & 21 C.F.R. 1306.22(f)(3) *	**C**	**N/I**	**N/C**	**U**	**N/A**
Daily back-up of system					X
Maintain the original prescription					X
Prevent modification or manipulation					X
Daily print-outs or log book (requires signature)					X
Type of automation:					
EDSS Notes: No computers onsite for inspection - will review at first routine inspection.					
C-V OTC SALES	**C**	**N/I**	**N/C**	**U**	**N/A**
Log book for C-V OTC products (ex. cough syrups)—K.A.R. 68-20-22					X
Appropriate ID used/obtained/accepted for sale of C-V OTC products —K.S.A. 65-1643(j)(1)(b) & K.A.R. 68-20-22(d)					X
Documentation of C-V OTC pseudoephedrine/ephedrine sales—K.S.A. 65-1643(j)(1)(B) & K.A.R. 65-16,102					X
Lawful prescription for C-V pseudoephedrine—K.S.A. 65-1643(j)(2)					X
C-V OTC Sales Notes:	No OTC sales				
VACCINATIONS/IMMUNIZATIONS	**C**	**N/I**	**N/C**	**U**	**N/A**
Vaccination protocol—K.S.A. 65-1626(vvv)					X
Documentation of study & training—K.S.A. 65-1635a(a)					X
Current CPR certificate—K.S.A. 65-1635a(a)					X
Written immunization record—K.S.A. 65-1635a(b)					X
Record reported—K.S.A. 65-1635a(b)					X
Review of					
To whom:					
Vacc./Immun. Notes:	Will not be administering				
INCIDENT REPORTS—K.A.R. 68-7-21(b)(4) & K.A.R. 68-7-12b(c)	**C**	**N/I**	**N/C**	**U**	**N/A**
Timely preparation					X
Name, address, age, & phone number of complainant					X
Name of all employees involved					X
License/Registration number of all employees involved					X
Signature of all employees involved					X
Date of incident					X
Date of report					X
Description of the incident					X
Prescriber's name					X
Prescriber contacted					X
Incident Report Notes: Pre-opening inspection. Does not apply for this inspection.					

CQI REPORTS—K.A.R. 68-19-1	C	N/I	N/C	U	N/A
Meet each quarter of each calendar year, every 90 days					X
PIC in attendance at the meeting *					X
List of persons in attendance					X
List all reportable incident reports					X
Review all reportable incident reports					X
List newsletters reviewed					X
Description of preventative steps for each incident reviewed					X
CQI Notes: Pre-opening inspection. Does not apply for this inspection.					
REVIEW OF INVENTORY AND INVOICE RECORDS	**C**	**N/I**	**N/C**	**U**	**N/A**
Annual inventory of controlled substances—K.A.R. 68-20-16					X
Change of PIC controlled substances inventory—K.A.R. 68-7-12(e)&(f) *					X
C-II inventory filed separately—K.A.R. 68-20-16					X
C-II invoices filed separately—K.A.R. 68-20-16					X
CIII-V invoices filed separately or readily retrievable—K.A.R. 68-20-16					X
Drugs received from registered sources—K.S.A. 65-1643(c)					X
DEA 222 forms completed—21 C.F.R. 1305.12 & 1305.13					X
DEA 222 forms for C-II transfers—K.A.R. 68-20-17					X
Controlled substance ordering system—21 C.F.R. 1305.21					X
Power of attorney—21 C.F.R. 1305.05					X
Date:					
Date(s):					
Review of Inventory and Invoice Notes: Pre-opening inspection. Pending DEA permit.					
REVIEW OF PRESCRIPTION FILES	**C**	**N/I**	**N/C**	**U**	**N/A**
Files (C-II separate)—21 C.F.R. 1304.04(h) & K.A.R. 68-20-16(a)					X
Controlled substance files are void of preprinted prescriptions—K.A.R. 68-20-18(c)					X
C-II prescriptions properly canceled—K.A.R. 68-20-19(e)					X
Controlled substances filled prior to expiration of prescriptions—K.A.R. 68-20-19 & K.A.R. 68-20-20					X
Dating on C-II scripts is compliant (no changes)					X
Issuance of multiple C-II prescriptions—21 C.F.R. 1306.12					X
Dispensing in strict conformity—K.S.A. 65-1637(g)&(h) & K.S.A. 65-657(n)					X
Controlled substance prescriptions have full address of patient (no PO Boxes)—K.A.R. 68-20-18(c)					X
Controlled substance prescriptions have address and DEA number of prescriber—K.A.R. 68-20-18(c)					X
Fax number or agent ID—K.S.A. 65-1637(b) & K.A.R. 68-20-18(d)(1)					X
First and last name of the agent—K.S.A. 65-1637(b)					X
Supervising doctor for APRN/PA —K.S.A. 65-28a08(b), K.S.A. 65-1130(d), K.A.R.100-28a-13(f), & K.A.R. 60-11-104a(c)					X
LTCF/Hospice identified—21 C.F.R .1306.11(f)&(g)					X
Storage of electronic prescriptions—K.A.R. 68-9-1					X
Review of					
Review of					
Format:					
Review of Prescription Files Notes: Pre-opening inspection only - no dispensing has occurred.					
PRESCRIPTION LABELS—K.A.R. 68-7-14	**C**	**N/I**	**N/C**	**U**	**N/A**
Name, address, & telephone number of dispensing pharmacy					X
Name of prescriber or PA/APRN & physician					X
Full name of patient					X
Prescription number					X
Date filled or refilled					X
Adequate directions for use					X
Beyond-use date					X
Brand name or generic name of the drug or device					X
Name of manufacturer or distributor					X
Strength of drug					X
Quantity dispensed					X
Auxiliary labels if needed					X
Prescription Labels Notes: Pre-opening inspection only - will review at first routine inspection for full compliance.					
PHARMACY PROCESSES	**C**	**N/I**	**N/C**	**U**	**N/A**
Provides FDA required medication guides with all new & refill prescriptions—21 C.F.R. 208.24					X

Provides side effect statement with all new and refill prescriptions—21 C.F.R. 209.11					X
Child proof packaging—FDA Poison Prevention Packaging Act*					X
Observation of counseling—K.A.R. 68-2-20(b)(5)					X
Medication profile review—K.S.A. 65-1642(c) & K.A.R. 68-2-20(b)(9)					X
Provides direct supervision—K.S.A. 65-1626(n)					X
Documentation of pharmacist performing prescription verification—K.A.R. 68-2-20(b)					
Resale of medication prohibited except for limited exceptions—K.A.R. 68-12-2					
Pharmacy Processes Notes: Pre-opening inspection only					
TECHNICIANS	**C**	**N/I**	**N/C**	**U**	**N/A**
Ratio of pharmacy technicians to pharmacists—K.A.R. 68-5-16					X
Maintain a list of the names of pharmacy technicians—K.S.A. 65-1663(i)					X
Technician training—K.A.R. 68-5-15(d)(2) *					X
Annual review of technician training course—K.A.R. 68-5-15(d)(1) *					X
Supervision of technicians—K.S.A. 65-1626(n)					X
Ratio during inspection:					
Technicians Notes: No techs on site - pre-opening inspection only - currently hiring.					
LTC FACILITY	**C**	**N/I**	**N/C**	**U**	**N/A**
Drug distribution to LTC facilities—K.A.R. 68-7-10					X
E-Kit supply and maintenance—K.A.R. 68-7-10(d)					X
Automation housed at LTC facilities—K.A.R. 68-9-3 *					X
Controlled substance in automation at LTC facilities—21 C.F.R. 1301.27 *					X
Stocked by:					
DEA number of automation:					
LTC Notes: pre-opening inspection only					
PREPACKAGING/REPACKAGING—K.A.R. 68-7-15	**C**	**N/I**	**N/C**	**U**	**N/A**
Stored according to manufacturer's recommendation					X
Proper control system for recall purposes					X
Expiration date not to exceed the shorter of 12 months, manufacturer's exp. date, or packaging limitations					X
Type of packaging used:					
Prepackaging/Repackaging Notes: pre-opening inspection only					
PREPACKAGING/REPACKAGING LABELS—K.A.R. 68-7-16	**C**	**N/I**	**N/C**	**U**	**N/A**
Brand or generic name					X
Name of manufacturer or distributor for generic drugs (may be kept in a repackaging log)					X
Strength and quantity					X
Lot number (may be kept in a repackaging log)					X
Date repackaged (may be kept in a repackaging log)					X
Person responsible for packaging (may be kept in a repackaging log)					X
Expiration date					X
Auxiliary labels if necessary					X
Prepackaging/Repackaging Labels Notes: pre-opening inspection only					
AUTOMATED DRUG DELIVERY SYSTEMS—K.A.R. 68-9-2 *	**C**	**N/I**	**N/C**	**U**	**N/A**
Good working order with accuracy in selection					X
All drugs removed and returned are secure and accounted for					X
All wasted/discarded drugs are secure and accounted for					X
Loaded accurately					X
Medications stored per manufacturers storage requirements					X
Loading and unloading limited to R. Ph, Pharm. Intern, Pharm. Tech or Licensed Nurse					X
Maintain a current list of approved individuals to unload any drug					X
All drugs are compliantly packaged					X
Track lot numbers and expiration date of containers					X
Preventive maintenance and sanitation					X
Type of automated drug delivery system:					
Automated Drug Delivery System Notes:					
SHARED SERVICES—K.A.R. 68-7-20	**C**	**N/I**	**N/C**	**U**	**N/A**
Common electronic file or appropriate technology					X
Same owner or written contract					X
Joint policies and procedures manual					X
Maintain records identifying each R. Ph, Pharm. Intern, Pharm. Tech in all pharmacy processes					X
Mechanism for tracking order					X
All pharmacies identified on prescription label					X

Shared order processing pharmacy:	SelectRX
Shared order filling pharmacy:	
Shared Services Notes: pre-opening inspection only - will review at first inspection for full compliance	

This report created on: 2/4/2025

Kansas State Board of Pharmacy

800 SW Jackson St. Suite 1414
Topeka, Kansas 66612-1244
Phone (785) 296-4056
Fax (785) 296-8420

email pharmacy@ks.gov
www.pharmacy.ks.gov

2-124646
STEELE, WHITTNEY DANIELLE
SelectRx KS, LLC
418 W. Frontier Lane
Olathe, KS 66061

Schedules 2, 2n, 3, 3n, 4, 5

STATE OF KANSAS
STATE BOARD OF PHARMACY

N° 2-124646

PHARMACY REGISTRATION

This registration Must Be Renewed Annually by **June 30th**

SelectQuote Ventures, Inc. *as owner*

and STEELE, WHITTNEY DANIELLE *as P.I.C.*

has complied with the Pharmacy Act of the State of Kansas providing for the registration or licensing of ***Pharmacies or Drug Store*** *within the State of Kansas, and is hereby granted a registration to establish and maintain a pharmacy*

to be known as **SelectRx KS, LLC**

at **418 W. FRONTIER LANE** **OLATHE** **KANSAS**

from this date until **6/30/2025** *, unless this registration is surrendered, or revoked or suspended by the Kansas State Board of Pharmacy.*

The original registration issued **January 31, 2025.**

LICENSED PHARMACIST IN CHARGE

Name STEELE, WHITTNEY DANIELLE *Certificate No.* 1-102843

Date of Change: 1/31/2025

KANSAS STATE BOARD OF PHARMACY

By _____ Executive Secretary

THIS REGISTRATION MUST BE POSTED IN A CONSIPICUOUS PLACE - NOT TRANSFERABLE
DO NOT DESTROY - Return to Secretary for change in ownership, location or pharmacist in charge

Search Again

Facility/Provider Information

The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board. Note Pharmacy Technicians issued after January 1, 2019 will now have a 24- prefix for their registration number until they provide proof of passage of the PTCB or ExCPT certification examination.

General

License #:	2-124646	Status:	Active
Name or Business:	SelectRx KS, LLC	Issue Date:	1/31/2025
Business Owner:	SelectQuote Ventures, Inc.		
Address:	418 W. Frontier Lane Olathe, KS 66061	Expiration Date:	6/30/2025
Classification:	Pharmacy/Facility	On Probation:	**No**
License Type:	Pharmacy	Discipline on File:	**No** Submit Complaint

Licenses

L/P/R #	Description	Effective	Issued	Expires	Status
2-124646	Pharmacy Permit	1/31/2025	1/31/2025	6/30/2025	Active

Notes

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS5082247	02-29-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-05-2025

SELECTRX KS, LLC
418 W. FRONTIER LN
OLATHE, KS 66061

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (9/2016)

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FT3470072
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: The Art of Medicine

Physical Address: 1335 Mount Vernon St

City: Philadelphia State: PA Zip: 19123

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 215-238-9055 Toll Free # (NAC 639.708, NRS 639.23286): 844-864-7579

Fax: 215-238-9033 Contact Email: compliance@theartofmed.com

Website: theartofmed.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jack Korbutov

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24493

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jack Korbutov	NV Pharmacist Registration #: 24493
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): N/A

Corporation/Organization Name: The Art of Medicine, LLC

Mailing Address: 1335 Mount Vernon St

City: Philadelphia State: PA Zip: 19123

Telephone: 2152389055 Email: compliance@theartofmed.com

Contact Person Name: Jack Korbutov

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for The Art of Medicine (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jack Korbutov

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/17/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jack Korbutov hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for The Art of Medicine (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 17 day of FEBRUARY, 20 25

Notary Public

Commonwealth of Pennsylvania - Notary Seal
CHRISTOPHER ELLIOTT SCOTT,JR., Notary Public
Philadelphia County
My Commission Expires March 1, 2025
Commission Number 1391147

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jack Korbutov

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/17/25

Date

Board Use Only	Date Received: 3/4/25	Amount: $500 - CK 61836438-3

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: The Art of Medicine

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending

Physical Address: 1335 Mount Vernon Street

City: Philadelphia State: PA Zip: 19123

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 844-864-7579 Website: theartofmed.com

Licensing Company Email: compliance@theartofmed.com

Section 2: Personal Information

First: Jack Middle: David Last: Korbutov

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Wallingford State: PA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Council Rock High School south			09/2001-05/2005	
Address		City	State	Zip
2002 Rock Way		Holland	PA	18966
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Philadelphia College of Philadelphia			08/2005-05/2011	
Address		City	State	Zip
600 S. 43rd sr		Philadelphia	PA	19104
Diploma/Degree obtained, if any				
PharmD				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2014-05/2023	[redacted]	Philadelphia	PA	[redacted]
05/2023-Present	[redacted]	Wallingford	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
The Art of Medicine			05/12-Present	
Business Address		**City**	**State**	**Zip**
1335 Mount Vernon Street		Philadelphia	PA	19123
Phone	**Title**			
844-864-7579	President/PIC			
Description of Duties				
I am the owner and pharmacist-in-charge of The Art of Medicine. I oversee all pharmacy operations to ensure compliance with state and federal laws as well as relevant USP chapters.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jack Korbutov

Print Name (First, Last)

Jack Korbutov — 03/18/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Miami Dade

I, Jack Korbutov, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jack Korbutov — 03/18/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 18th day of March 2025.

Armando Smith

Notary Public Signature

ARMANDO SMITH
Notary Public - State of Florida
Commission # HH610345
Expires on November 6, 2028

Notarized remotely online using communication technology via Proof.

(Seal)

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	The Art of Medicine, LLC
Request Type:	Subsistence Certificate
Request No.:	045885029
Receipt No.:	001291266
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	March 13, 2012
Status:	Active

Issuance Date: November 08, 2024
File No.: 0004094182

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

The Art of Medicine, LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

THE ART OF MEDICINE

1335 MT VERNON ST
PHILADELPHIA, Pennsylvania, 19123

Phone:
Owner: THE ART OF MEDICINE, LLC

LICENSE

License No: PP482313
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 01/10/2025
Inspection Result: Passed

Remarks: Pharmacist on duty Jack Korbutov RP445776. Pharmacist in charge and Designated Person Jack Korbutov stated to me that the pharmacy will follow all USP 795/800 Guidelines.

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

ALLEN SOLOMON	1/10/2025 10:58:35 AM	Jack Korbutov - RP445776
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

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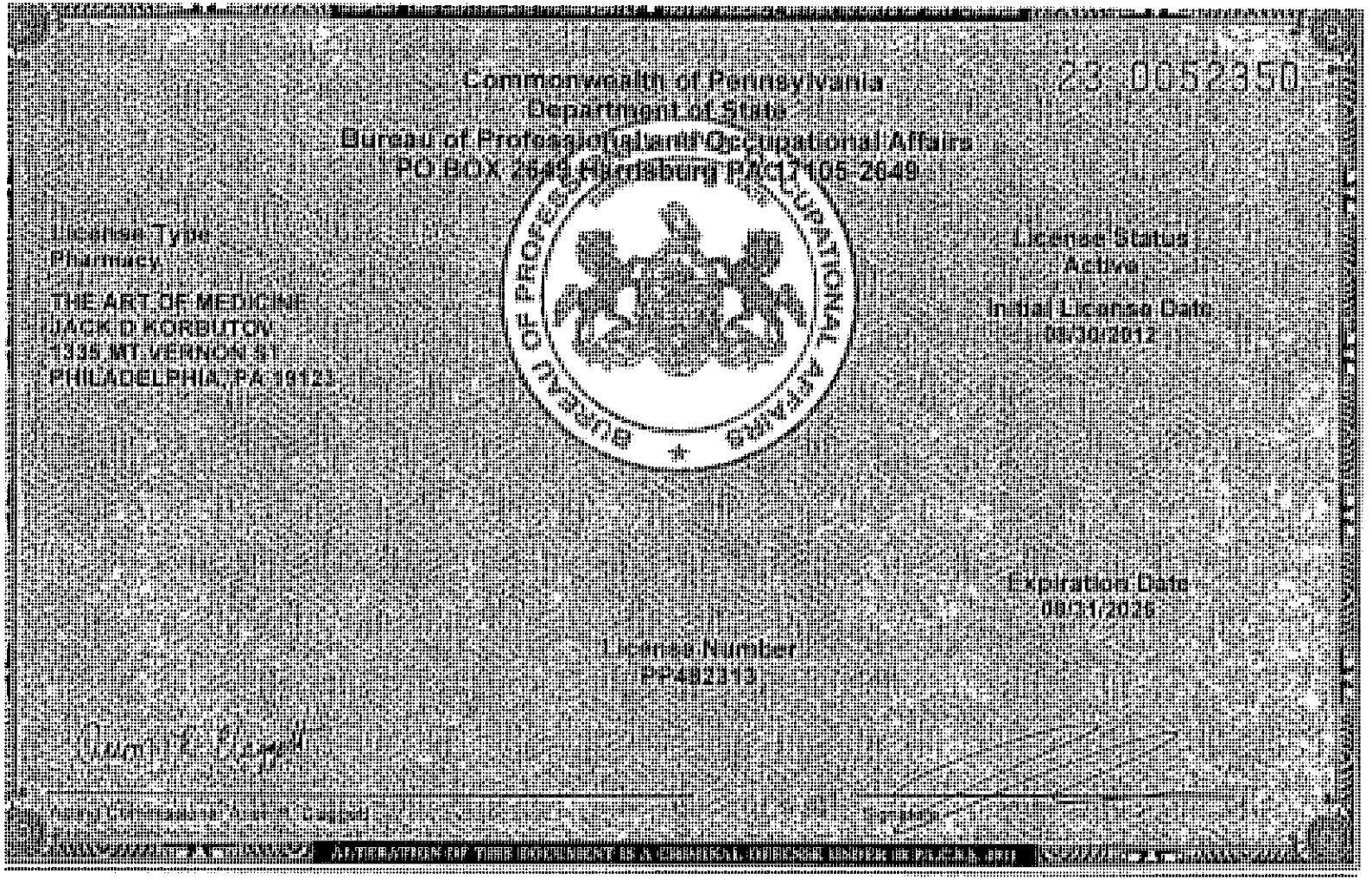
Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO



Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

23 0052350

License Type
Pharmacy

THE ART OF MEDICINE
JACK D KORBLITON
1335 MT VERNON ST
PHILADELPHIA, PA 19123

License Status
Active

Initial License Date
04/30/2012

Expiration Date
09/31/2026

License Number
PP482313

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

01/31/2025

License Information

THE ART OF MEDICINE

1335 MT VERNON ST
PHILADELPHIA, Pennsylvania 19123

Board/Commission:	State Board of Pharmacy	Status Effective Date:	11/18/2019
LicenseType:	Pharmacy	Issue Date:	08/30/2012
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2025
License Number:	PP482313	Last Renewal:	07/06/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
JACK D KORBUTOV	Business Relationship	Pharmacist	RP445776	Active	08/30/2012	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT3470072	11-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-04-2024

THE ART OF MEDICINE
1335 MOUNT VERNON ST
PHILADELPHIA, PA 191233211

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			■ Long Term Care
	* Current license #: PH_____		■ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	■ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Luxor Pharmacy Corp DBA The Medicine Shoppe

Physical Address: 10465 Arlingtone Ave Ste 300

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 951 406 1521 Toll Free # (NAC 639.708, NRS 639.23286): 888 390 0702

Fax: 951 406 1520 Contact Email: luxor@medicineshoppe.us

Website: _____

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220): Peter Sayeh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21365

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Peter Sayeh	NV Pharmacist Registration #: 21365
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): NA

Corporation Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Date of SEC Registration: NA | SEC Registration Number: NA | Stock Exchange Symbol: NA

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any):

Corporation/Organization Name: Luxor Pharmacy Corp DBA The Medicine Shoppe

Mailing Address: 10465 Arlington Ave Ste 300

City: Riverside State: CA Zip: 92505

Telephone: 951 406 1521 Email: luxor@medicineshoppe.us

Contact Person Name: Samer Baskhayroun

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: NA

Business Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Luxor Pharmacy Cop. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Samer Beshkayroun

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12-19-2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Samer Beskhayroun hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Luxor Pharmacy CorpDBAThe Medicine Shoppe (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 30 day of December, 2024

Notary Public

See Attached California notary jurat

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 30 day of December, 2024, by Samer BESKHAYROUN, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal) Signature

Affidavit for Pharmacy etc.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samer Beshnagrouh.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12-19-2024

Date

Board Use Only	Date Received: 1/16/25	Amount: $500 - CK 1560

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	LUXOR PHARMACY CORP
Entity No.:	5591061
Registration Date:	03/20/2023
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of December 26, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 278497542

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 03/12/2024 Inspector: Trang Song

Firm: THE MEDICINE SHOPPE Phone: (951) 406-1521

Address: 10465 Arlington Ave ste 300 City: Riverside Zip: 92505

Ownership: CORPORATION

Permit #: PHY59236 Permit Exp: 1/1/2026 DEA#: FT3913464 DEA Exp: 11/30/2026

Date of Self Assessment Form: 02/22/2024 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 9AM-6PM Hours Saturday 9AM-2PM Hours Sunday: CLOSED

PIC JENNY VU RPH61940 Administrator ___

RPH Consultant ___

Staff	RPH Name:	License #:	Staff Name:	License #:
	SON T TRAN	RPH43488	JESSICA DELACRUZ	TCH90750
	Peter Sayeh	RPH76322	LUIS M CERON	TCH46879
	JOHN IBRAHIM K KHALIL	RPH85556	MARIA MURO	CLERK
			VICTORIA Z DIAZ	TCH170709

Inspector Remarks:

Retail pharmacy, dispensed about 70-80Rxs daily, staffed with 1RPH/2TCH/1 clerk. Pharmacy offers delivery and pharmacist initiated immunization services. Pharmacy does not dispense compounded drug preparations, and does not participate in drug take back program.

Reviewed:

Notice to Consumer, Point to Your Language poster visible/posted. Interpretive services provided by Language Scientific.

Pharmacy Permit - Original board issued pharmacy license & current renewal must be posted where they maybe clearly read by the purchasing public, per BPC 4058.

CURES - transmitting

DEA Inventory - Discussed requirements per CFR 1307.11. PIC to provide most recently completed DEA inventory.

Rx script - 99% prescriptions dispensed are received electronically

Rx Label - Patient centered. Pharmacy occasionally dispensed prescriptions with translated direction for use. Reminder regarding BPC 4076.6: if translated directions for use appear on a prescription container or label, the English language version of the direction for use shall also appear on the container or label or with supplemental document. Dispensed opioid prescriptions contain caution statement required per BPC 4076.7

Consultation - no patients to observe. Reviewed sample prescriptions made ready for delivery. Discussed requirements per CCR 1707.2(b)(1)(A-C). PIC to provide proof of compliance.

Sink - Gold running water available but no hot running water available during inspection. See order of correction

Refrigerator - Temp=5.8C; reviewed log. Discussed proper/accurate, consistent documentation of freezer and refrigerator temp.

Immunization - pharmacy offers pharmacist initiated immunization. Recommend BUD documented directly on package, based on recommendation from manufacturer. Training certificate and CPR, issued 12/20/21 available for RPH Tran

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

- Controlled substances - stored in secured safe, bolted to the floor/wall.
- Controlled substances reconciliation - CII reconciliation from 10/01/2023 to 01/01/2024 - no unexplained discrepancy per PIC. C3-5 reconciliationcompleted from 10/01/2023 to 01/01/2024.
- Auto refills - . See education/discussion below.
- Policy/Procedures - uses license protection handbook
- Self Assessment - Last assessment, form 17M-13 (Rev 10/14) completed by PIC dated 02/22/2024.
- Computer software - Digital Rx
- Wholesaler – Cardinal; CII orders placed by CSOS - Reminder to endorse, electronically, quantity and date of CII upon receipt.
- Reverse Distributor - Guaranteed Returns

Education/Discussion: PIC/Pharmacy to review and revise policies/procedures as needed to reflect new regulations/amended regulations.

1. Effective 1/1/2023 - Amended CCR 1715.65 adopted: Inventory Activities and Inventory Reconciliation Reports of Controlled Substances. This amended regulation identifies four non-Schedule II controlled substances that must be inventoried at least every 12 months; specifies when all other controlled substances must be inventoried. See full adopted regulation on the board's website,

2. Effective 10/1/2022: CCR1708.1 - Notification of Temporary Closure: notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. A temporary closure shall not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days.
3. CCR 1717.5 Auto Refills - Effective 7/1/2024
4. Effective 4/1/22 - Amended § 1715.6 Reporting Drug Loss.
5. Script Newsletter, latest edition August 2022 available on board website

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) _____

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

License No. PHY 59236
Receipt No. 42992028

Valid Until: 1/1/2026

THE MEDICINE SHOPPE
10465 ARLINGTON AVE #300
RIVERSIDE, CA 92505

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.

The official status of this license can be verified at www.pharmacy.ca.gov

This permit is valid only at the address shown.

---- NON-TRANSFERABLE ------ POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

CALIC100 RENWALR 10282024 380117 SEQID5884

THE MEDICINE SHOPPE
10465 ARLINGTON AVE #300
RIVERSIDE, CA 92505
5884

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

List of Officers and Directors

Luxor Pharmacy Corp DBA The Medicine Shoppe Pharmacy #2213

CEO - Samer Beskhayroun - 20%

CFO - Awni Alfakhouri - 40%

Officer - Raghda Alfakhouri - 40%

List of all Stockholders and their percentages

Luxor Pharmacy Corp DBA The Medicine Shoppe Pharmacy #2213

CEO - Samer Beskhayroun - 20%

CFO - Awni Alfakhouri - 40%

Officer - Raghda Alfakhouri - 40%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Luxor Pharmacy Corp DBA The Medicine Shoppe

Pharmacy/Wholesaler License # (if applicable): PHY59236

Physical Address: 10465 Arlington Ave Ste 300

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 9514061521 Website: www.medicineshoppe.com

Licensing Company Email: Luxor@medicineshoppe.us

Section 2: Personal Information

First: Samer Middle: Malak Sadek Last: Beskhayroun

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Riverside State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Faculty of Pharmacy Cairo University		09/99-06/04	
Address	**City**	**State**	**Zip**
El Qasr El Einee	Cairo	NA	NA
Diploma/Degree obtained, if any			
Bachelor Degree of Pharmaceutical Science			

School Name		From - To (MM/YY – MM/YY)	
Gamal Abd Al Masser High School		09/96-06/99	
Address	**City**	**State**	**Zip**
Batl El Salam St	El Fayoum Egypt	NA	NA
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21-Current	[redacted]	Chino Hills	CA	[redacted]
06/17-05/21		Diamond Bar	CA	
9/15-05/17		Diamond Bar	CA	
06/13-08/15		El Fayoum	Egypt	

Question 7: A designated representative must provide proof that he or she has been employed for at least 6000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of dangerous drugs, related to prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: E&E Pharmaceuticals Corp				From - To (MM/YY – MM/YY): 12/20-Current
Business Address: 11801 Pierce St		City: Riverside	State: CA	Zip: 92505
Phone: 951 710 3151	Title: Operation Manager			Number of Employed Hours: 7840
Description of Duties: Supervising Multiple Pharmacies				

Business Name: Owel Western Pharmacy				From - To (MM/YY – MM/YY): 01/17-11/20
Business Address: 1009 W San Bernardino Rd.		City: Covina	State: CA	Zip: 91722
Phone: 626 209 8160	Title: Pharmacy Technician + Intern Pharmacist			Number of Employed Hours: 7680
Description of Duties: Filling/Giving orders				

Business Name: Global Napi Pharmaceuticals				From - To (MM/YY – MM/YY): 01/09-12/16
Business Address: 207 Ramsis St		City: Cairo	State: NA	Zip: NA
Phone: 0123607598	Title: Medical Representative			Number of Employed Hours: 1280
Description of Duties: Marketing for Medications				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			Number of Employed Hours:
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samer Besharat.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-30-2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Riverside

I, Samer Besharat, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-30-2024

Date

Subscribed and Sworn to before me this 30 day of December 2024

Notary Public Signature

See Attached California Notary Jurat.

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 30 day of December, 2024, by Samer BesKhayroun, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal)

Signature

Designated Representative Application

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Luxor Pharmacy Corp DBA The Medicine Shoppe

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable): PHY 59236

Physical Address: 10465 Arlington Ave Ste 300

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 9514061521 Website: www.medicineshoppe.com

Licensing Company Email: luxor@medicineshoppe.us

Section 2: Personal Information

First: Samer Middle: Malak Sadek Last: Beskhayroun

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Riverside State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Faculty of Pharmacy Cairo University		09/99-06/04	
Address	**City**	**State**	**Zip**
El Qasr El Einee	Cairo	NA	NA
Diploma/Degree obtained, if any			
Bachelor Degree of Pharmaceutical Science			

School Name		From - To (MM/YY – MM/YY)	
Gamal Abd Al Masser High School		09/96-06/99	
Address	**City**	**State**	**Zip**
Batl El Salam St	El Fayoum Egypt		
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21-Current	[redacted]	Chino Hills	CA	[redacted]
06/17-05/21		Diamond Bar	CA	
09/15-05/17		Diamond Bar	CA	
06/13-08/15		El Fayoum	Egypt	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
E&E Pharmaceuticals Corp			12/20-Current
Business Address	**City**	**State**	**Zip**
11801 Pierce St	Riverside	CA	92505
Phone	**Title**		
951 710 3151	Operation Manager		
Description of Duties			
Supervising Multiple Pharmacies			

Business Name			From - To (MM/YY – MM/YY)
Owel Western Pharmacy			01/17-11/20
Business Address	**City**	**State**	**Zip**
1009 W San Bernardino Rd	Covina	CA	91722
Phone	**Title**		
626 209 8160	Pharmacy Tech + Intern Pharmacist		
Description of Duties			
Filling / Giving orders			

Business Name			From - To (MM/YY – MM/YY)
Global Napi Pharmaceuticals			01/09-12/16
Business Address	**City**	**State**	**Zip**
207 Ramsis St	Cairo	NA	NA
Phone	**Title**		
0123607598	Medical Representative		
Description of Duties			
Marketing for Medications			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samer Beshnaeyroun

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-30-2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Samer Beshnaeyroun, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-30-2024

Date

Subscribed and Sworn to before me this 30 day of December 2024.

Notary Public Signature

California Notary Jurat

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 30 day of December, 2024, by Samer Beskhayroun, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal)

Signature

Personal History Application

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Luxor Pharmacy Corp. DBA The Medicine Shoppe

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PHY 59236

Physical Address: 10465 Arlington Ave Ste 300

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: 9514061521 Website: www.medicineshoppe.com

Licensing Company Email: luxor@medicineshoppe.us

Section 2: Personal Information

First: Awni Middle: Last: Alfakhouri

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Corona State: CA Zip: 92883

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Al-Salt Secondary School For Boys			08/67-06/71	
Address	**City**		**State**	**Zip**
Al-Manshieh, As-Salt Jordan				
Diploma/Degree obtained, if any				
High School Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/15-Present	[redacted]	Corona	CA	[redacted]
09/13-04-15	[redacted]	Corona	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sky Pharma Corp			12/14-present	
Business Address		**City**	**State**	**Zip**
11801 Pierce St		Riverside	CA	92505
Phone	**Title**			
	Administrator			
Description of Duties				
Administration & office work				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Awni Alfakhouri

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-18-24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Riverside

I, Awni Alfakhouri, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/2024

Date

Subscribed and Sworn to before me this 12 day of 18/2024.

Notary Public Signature

See Attached California Notary Jurat

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 18 day of December, 2024, by Awni AlFakhouri, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal)

Signature

Personal History Application

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Luxor Pharmacy Corp. DBA The Medicine Shoppe

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PHY 59236

Physical Address: 10465 Arlington Ave Ste 300

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: 9514061521 Website: www.medicineshoppe.com

Licensing Company Email: luxor@medicineshoppe.us

Section 2: Personal Information

First: Raghda Middle: Last: Alfakhouri

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Corona State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Al-Salt Secondary School For Girls			08/68-06/72	
Address	**City**		**State**	**Zip**
Prince Hamza St, As-Salt Jordan				
Diploma/Degree obtained, if any				
High School Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/15-Present	[redacted]	Corona	CA	[redacted]
09/13-04-15	[redacted]	Corona	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner or related capacity within the last 10 years.

Business Name: Pyramids Pharmacy Corp.			From - To (MM/YY – MM/YY)
Business Address: 1121 S State St.	City: Hemet	State: CA	Zip: 92543
Phone: 951 652 5968	Title: secretary		
Description of Duties: Financial officer.			

Business Name: Genesis Pharmacy Corp.			From - To (MM/YY – MM/YY): 5/15/23 - Present
Business Address: 31946 Mission Trail St A-1	City: Lake Elsinore	State: CA	Zip: 92530
Phone: 9512451373	Title: secretary		
Description of Duties: Financial officer.			

Business Name: Glory Pharmacy Corp.			From - To (MM/YY – MM/YY): 5/15/23 - Present
Business Address: 9675 Monte Vista Ave ste A	City: Montclair	State: CA	Zip: 91763
Phone: 909 542 9365	Title: CFO		
Description of Duties: Financial officer.			

Business Name:			From - To (MM/YY – MM/YY)
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY)
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Raghda Alfakhouri

Print Name (First, Last)

رغده فاخوري

Original Signature (electronic, copies or stamps not accepted)

12/18/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

رغده فاخوري

Original Signature

12/18/2024

Date

Subscribed and Sworn to before me this 18 day of December, 2024.

Notary Public Signature

See Attached California Notary Jurat

(Seal)

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State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 18 day of December, 2024, by Raghda Alfa-Khouri, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal)

Signature

Personal History Application

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT3913464	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-14-2024

THE MEDICINE SHOPPE
LUXOR PHARMACY CORP
10465 ARLINGTON AVE STE 300
RIVERSIDE, CA 92505

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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WASHINGTON D.C. 20537

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RIVERSIDE, CA 92505

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Form DEA-223 (9/2016)

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02455	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Independent/Mail Order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FU6551863 ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: US MED, LLC

Physical Address: 8491 NW 17th Street, Suite 102

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip: 43017

Telephone: 866-938-4482 Toll Free # (NAC 639.708, NRS 639.23286): 866-938-4482

Fax: 866-223-7369 Contact Email: licensure@cardinalhealth.com

Website: www.USMED-RX.com

Nevada Business License # (if applicable) NV20212138349

Supervising/Managing Pharmacist Name (NRS 639.220): Adrienne Michelle Horn

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19438

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Adrienne Michelle Horn	NV Pharmacist Registration #: 19438
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Florida

Parent Company (if any): US Med Acquisition, Inc. (Parent Company of US MED, LLC)

Corporation Name: Cardinal Health Inc. (Ultimate Holding Company)

Mailing Address: 7000 Cardinal Place

City: Dublin State: OH Zip: 43017

Telephone: 614-757-5000 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983 | SEC Registration Number: 721371 | Stock Exchange Symbol: CAH

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director (title) for US MED, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Keegan David Chamberlain

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/20/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Keegan David Chamberlain hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director (title) for US MED, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of February, 2025

Notary Public

Michael Williams
Notary Public, State of Ohio
My Commission Expires 05-05-2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keegan David Chamberlain

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

02/20/2025
Date

Board Use Only	Date Received: 2/24/25	Amount: $500 ck 10924249

Nevada BOP Pharmacy Application for
US MED, LLC

List of all Officers and Directors

Officer/Director Name	Title
Robert Evan Schlissberg	President
Keegan David Chamberlain	Director
John Henry Martin Jr.	SVP, Tax
Brent Matthew Withrow	Asst. Treasurer
Anthony F. Alvarez	Secretary

Cardinal Health - Medical Distribution,
Quality & Regulatory Affairs
7000 Cardinal Place
Dublin OH 43017
cardinalhealth.com
614.553.3076 tel

licensure@cardinalhealth.com email

CardinalHealth

Top 4 Corporation Shareholders

Name	Percentage of Ownership
Vanguard Fiduciary Trust Co.	12.65 %
BlackRock Advisors LLC	9.478 %
STATE STREET CORPORATION	5.600 %
Geode Capital Management LLC	2.359 %

State of Florida
Department of State

I certify from the records of this office that US MED, LLC is a limited liability company organized under the laws of the State of Florida, filed on August 10, 2015, effective February 19, 1999.

The document number of this limited liability company is L15000134714.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on February 13, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifth day of December, 2024

Secretary of State

Tracking Number: 2368558639CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 16097
Insp # 191593

NAME	PERMIT NUMBER	DATE OF INSPECTION
US MED, LLC	23521	11/06/2024
DOING BUSINESS AS		
STREET ADDRESS 8491 NW 17th ST STE #102	**TELEPHONE #** 866-938-4482	**EXT**
CITY MIAMI	**COUNTY** MIAMI-DADE	**STATE/ZIP** FL/33126

Additional Information

Business Operation Hours

Monday Hours 7:00 AM to 7:00 PM	Tuesday Hours 7:00 AM to 7:00 PM
Wednesday Hours 7:00 AM to 7:00 PM	Thursday Hours 7:00 AM to 7:00 PM
Friday Hours 7:00 AM to 7:00 PM	M-T-W-TH-F Y
Weekly Hours 7:00 AM to 7:00 PM	Monday Y
Tuesday Y	Wednesday Y
Thursday Y	Friday Y
Saturday Y	Sunday N
Sunday Hours Closed	Saturday Hours 8:00 AM to 12:00 AM

Registered Pharmacist / Intern / Tech

License # PS 49584	Licensee Name Terrel W. Bohannon
License Type Registered Pharmacists	
License # PS 51507	Licensee Name Anya C. Scott
License Type Registered Pharmacists	
License # PS 43414	Licensee Name Stephanie N. de la Rosa
License Type Registered Pharmacists	
License # RPT 42556	Licensee Name Jennifer D. Wilson
License Type Pharmacy Tech	
License # PS 52589	Licensee Name Adrienne Horn
License Type Registered Pharmacists	
License # RPT 65468	Licensee Name Jovany Pazos
License Type Pharmacy Tech	
License # RPT 4274	Licensee Name Daniel Lorand Willis
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FU6551863	

License Relations

Pharmacy Affiliate

HARROFF, JOHN	License #
HORVILLEUR, CAMILO	License #

RX DPT MGR/COR/POR

HORN, ADRIENNE MICHELLE	License # 52589

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *No controlled substances on stock.*	N/A
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A

Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	N/A

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Last CQI meeting conducted on: 09/27/2024. Wholesaler: Symple. Diagnostic. Pharmacy does not carry controlled substances. Diabetes supply ships thru UPS.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CASTILLO, ELIZABETH

Date:11/6/2024

Representative:

Adrienne Horn PDM

Date:11/6/2024

Your license number is PH 23521.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
DECEMBER 24, 2024	**PH 23521**	**146700**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

US MED, LLC
8491 NW 17TH ST STE #102
MIAMI, FL - 33126

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
DECEMBER 24, 2024	**PH 23521**	**146700**

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NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

US MED, LLC Expiration Date: **FEBRUARY 28, 2027**

REGISTRANT SIGNATURE

Department of Health

License Verification

Printer Friendly Version

US MED, LLC

License Number: PH23521

Data As Of 12/23/2024

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners

Profession	Pharmacy
License	PH23521
License Status	CLEAR/
Qualifications	Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	07/30/2008
Address of Record	8491 NW 17th ST STE #102 MIAMI, FL 33126
Discipline on File	No
Public Complaint	No

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

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February 7, 2025

Linda Aano
Us Med, Llc
2544 Campbell Place
Ste 150
Carlsbad, CA 92009

RE: License Certification for Us Med, Llc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH23521
ORIGINAL CERTIFICATION:	07/30/2008
EXPIRATION DATE:	02/28/2027
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FU6551863	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-15-2023

US MED, LLC
ATTN: LICENSING DEPT
8491 NW 17TH ST STE 102
DORAL, FL 331261025

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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DORAL, FL 331261025

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Form DEA-223 (9/2016)

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2024			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SY was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS27231, is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
MH was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS22622 is suspended. The suspension is stayed, and Respondent is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
JG pled guilty pursuant to a plea agreement and was convicted on one felony count of conspiracy in United States of America v. Jeffrey Dave Gress, United States District Court for Central District of California, Case 8:18-cr-00014-JLS. Respondent subsequently surrendered his DEA Registration No. FG3245455 by executing a DEA Form 104	No	Certificate of Registration No. CS20182 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $5,000and assessed $1,000 for attorney's fees and costs.	N/A
WP dispensed a prescription with erroneous directions for use which resulted in negative outcome to patient and failed to properly document medication counseling.	Yes	N/A	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.

WH performed data entry review and final product verification of a prescription and failed to detect erroneous directions for use which resulted in a negative outcome to the patient.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A
HB failed to properly document medication counseling for a prescription.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A
NSP compounded and dispensed drug products for 64 patients located in Nevada without holding a Nevada Pharmacy license, and the prescriptions dispensed may not have been compounded in compliance with Nevada Law.	No	N/A	Respondent fined $25,000 for the violations.
JK surrendered his Neveda Medical License No. 15386 to practice medicine for cause and no longer qualifies as a practitioner for registration to dispense controlled substances, and he committed acts that render his registration inconsistent with the public interest.	No	Certificate of Registration No. CS24228 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $2,000 and assessed $1,880.42 for attorney's fees and costs.	N/A
JB failed to disclose arrests and/or convictions on his original Pharmaceutical Technician in Training application. The Board held a hearing to address the charges against him on January 15, 2025, where he failed to appear, and a default order was taken.	No	Certificate of Registration No. PT28790 was revoked for a period of one year and assessed $511.46 in attorney's fees and costs.	N/A

AL transported a supply of controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers in a location other than a registered office in violation of Nevada Law. In addition, he knowingly or intentionally acquired controlled substances and/or dangerous drugs without a prescription and failed to query the controlled substance information in the PMP in violation of Nevada Law.	No	Certificate of Registration No. CS18089 is revoked. The revocation is stayed and placed on probation for a period of five years from the effective date of the Order. Respondent Lee shall not possess controlled substances except while on the premises of a hospital, a surgery center for ambulatory patients, or another medical facility where respondent is treating or caring for a surgical patient. Respondent Lee shall participate in four quarterly inspections from the effective date of the Order to January 14, 2026. Respondent fined $10,000 for the violations; and assessed $5,000 in attorney's fees and costs.	N/A
YS failed to secure dangerous drugs in a locked cabinet thereby allowing access to dangerous drugs by unlicensed personnel and administered drug products to a patient that were not acquired in compliance with Nevada Law.	No	YS accepts the Stipulation and Order as a public reprimand; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
RR worked as a pharmaceutical technician in training without obtaining a certificate of registration from the Board for the work location.	No	Certificate of Registration No. PT28825 is revoked, and Respondent may not petition for reinstatement for a period of one year from the effective date of the Order; and assessed $1,222.85 in attorney's fees and costs.	N/A

JS failed to disclose disciplinary order on his 2022 biennial renewal application for his Certificate of Registration No. CS09874. Respondent Siems issued sixty-eight controlled substance prescriptions on a suspended registration and permitted his medical assistants to forge and issue prescriptions for controlled substances.	No	Respondent's Certificate of Registration No. CS09874 is revoked, and Respondent may not petition for reinstatement for a period of two years from the effective date of the Order; Respondent fined $5,000 for the violations; and assessed $2,968.64 in attorney's fees and costs.	N/A
SCS engaged in the sale and or distribution of counterfeit HIV-1 drugs and transmitted falsified transaction records.	No	N/A	Respondent's License No. WH02131 is revoked, the revocation is stayed and Respondent placed on probation for a period of three years subject to the following conditions: a) Respondent shall pay a fine of $5,000 for the violations; b) assessed $3,584.10 in attorney's fees and costs; and c) Respondent shall be subject to an inspection by Board staff at respondent's expense.
WP is responsible for the acts of its employees who made an error in a prescription and failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	N/A	Respondent fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
JE failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	Respondent fined $500 for the violations; and assessed $500 in attorney's fees and costs.	N/A

CQ fined $500 for the violations; and assessed $500 in attorney's fees and costs.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
OM billed insurers for products that were never delivered to patients, failed to maintain an adequate system to resolve complaints by these patients, and failed to notify the Board of the departure of its facility administrator within three business days.	No	N/A	Respondent is not eligible to apply for a license or engage in business as a medical products provider or medical products wholesaler for a period of two years after the effective date of this Stipulation; Respondent shall notify the Board in writing if it becomes aware that any of its current officers, directors, shareholders, partner, or members have applied in an individual or representative capacity for a license to conduct business as a medical products provide or medical products wholesaler; Respondent shall accept this Stipulation as a public reprimand; Respondent shall refund payments or deposits as described in sections 1a, 1b, 1c, 1d, and 1f of the Investigate Report by June 30, 2025; Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.
WP is responsible for the acts of an employee who accessed protected health information for the purpose of learning personal information about a patient.	No	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.

MR accessed protected health information for the purpose of learning personal information about a patient.	No	Certificate of Registration No. PT28786 is revoked retroactively to October 31, 2024, and may not petition the Board for reinstatement for a period of one year from the effective date of the revocation; and assessed $500 in attorney's fees and costs.	N/A
EC diverted controlled substances from her place of employment at CVS Pharmacy.	No	Certificate of Registration No. PT18610 is revoked and may not petition for reinstatement for a period of one year.	N/A

5A

FILED
JAN 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **URI ASSA KRUTILIN, RPH,** **Certificate of Registration No. 18266,** **Respondent.**	**CASE NO. 18-052-RPH-S** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Uri Assa Krutilin , forfeited Certificate of Registration No. 18266, is hereby directed to appear before the Board for a hearing to show cause scheduled **for Wednesday, Match 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

2. On December 1, 2021, the Board entered default against Respondent pursuant to NRS 622A.320(1), NRS 639.244 and NRS 622A.350, and entered its Findings of Fact, Conclusions of (Default Order).

3. Respondent has failed to make payment of a fine of One Thousand Three Hundred Dollars ($1,300.00) pursuant to the Default Order.

4. Respondent has failed to make payment of Seven Hundred Forty-Nine Dollars ($749.00) for attorney's fees and investigative costs pursuant to the Default Order.

5. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapter 639, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 11th day of January 2025.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of January 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Uri Assa Krutilin
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

FILED
DEC 1 2021
NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OMNICARE OF LAS VEGAS, Pharmacy License No. PHC01949,** **URI ASSA KRUTILIN, RPH, Certificate of Registration No. 18266,** **Respondents.**	**CASE NO. 18-052-PH-S** **18-052-RPH--S** **FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND ORDER AS TO RESPONDENT URI ASSA KRUTILIN ONLY**

This matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Wednesday, December 1, 2021, in Las Vegas, Nevada. Courtney K. Lee, Esq., appeared and prosecuted the case before the Board. Respondent Omnicare of Las Vegas ("Omnicare"), Pharmacy License No. PHC01949 appeared by Omnicare representative Brian Convery and a Stipulation and Order as to Respondent Omnicare only was approved by the Board.

Respondent Uri Assa Krutilin, RPH ("Assa Krutilin"), Certificate of Registration No. 18266, did not appear. Assa Krutilin did not file an answer or notice of defense, which constitutes a waiver of right to a hearing pursuant to NRS 639.244. Assa Krutilin failed to appear, therefore an offer of proof of sufficient legal notice was submitted by Board coordinators', Shirley Hunting and Kris Mangosing, through their testimonies and proof of service documents submitted as Exhibit "1". The Board proceeded to consider and dispose of the case without Respondent Assa Krutilin pursuant to NRS 622A.350. Upon hearing the case, the Board determines the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

The allegations against Respondent Assa Krutilin, as stated in the Notice of Intended Action and Accusation ("Accusation") on file herein, and upon which the Board determines findings of fact, are as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Uri Assa Krutilin, RPh ("Assa Krutilin") held a Nevada Pharmacist Certificate of Registration No. 18266, issued by the Board.

2. Respondent Omnicare is a compounding pharmacy located on 1525 E. Sunset, #16, Las Vegas, Nevada.

3. Respondent Assa Krutilin is/was the managing pharmacist of Omnicare during the relevant timeframes.

4. On or about June 29, 2018, Board staff visited Omnicare at 8:00 a.m. Pharmacist L.T. was the only pharmacist present with eight (8) technicians.

5. Upon review of the work schedules, timeclock records, security door scan records, and sign in logs, the following violations were discovered:

a. On or about June 18, 2018, from 8:00 a.m. to 9:30 a.m., Pharmacist J.P. and L.T. were present with technicians J.F., F.B., W.M., D.R., M.R., J.B., and D.W., a ratio of 2:7.

b. On or about June 22, 2018, from 8:00 a.m. to 8:30 a.m., Pharmacists H.B. and L.T. were present with technicians J.F., F.B., K.F., M.E., A.D., C.F., and V.W., a ratio of 2:7.

c. On or about June 22, 2018, from 1:30 p.m. to 4:00 p.m., Pharmacists H.B. and Respondent Assa Krutilin were present with technicians F.B., K.F., L.K., A.D., N.K., N.P., J.B., and V.W., a ratio of 2:8.

d. On or about June 22, 2018, from 5:30 p.m. to 6:00 p.m., Pharmacists H.B. was present with technicians A.M., L.K., A.D., N.K., N.P., and V.W., a ratio of 1:6.

e. On or about June 22, 2018, from 6:30 p.m. to 8:00 p.m., Pharmacist J.P. was present with technicians A.M., L.K., N.K., N.P., and V.W., a ratio of 1:5.

f. On or about June 22, 2018, from 8:00 p.m. to 8:30 p.m., Pharmacist J.P. was present with technicians L.K., N.K., N.P., and V.W., a ratio of 1:4.

g. On or about June 25, 2018, from 8:00 a.m. to 8:30 a.m., Pharmacist L.T. was present with technicians J.F., A.M., K.F., A.D., M.R., and V.W., a ratio of 1:6.

h. On or about June 25, 2018, from 2:30 p.m. to 4:00 p.m., Respondent Assa Krutilin and Pharmacist J.P. were present with technicians F.B., K.F., M.R., N.P., V.W., R.B., J.B., and D.W., a ratio of 2:8.

i. On or about June 25, 2018, from 4:00 p.m. to 4:30 p.m., Respondent Assa Krutilin, Pharmacists B.K. and J.P. were present with technicians A.D., F.B., K.F., M.R., N.K., N.P., V.W., R.S., R.B., and D.W., a ratio of 3:10.

j. On or about June 25, 2018, from 4:30 p.m. to 5:00 p.m., Pharmacists B.K. and J.P. were present with technicians A.D., F.B., N.K., V.W., R.S., J.B., and R.B., a ratio of 2:7.

k. On or about June 29, 2018 at 8:00 a.m., Pharmacist L.T. was present with F.B., W.M., A.D., C.F., N.P., M.E., V.W., and J.B., a ratio of 1:8.

l. On or about June 29, 2018, from 4:00 p.m. to 4:30 p.m., Pharmacists H.B., and B.K. were present with technicians A.M., F.B., K.F., L.K., W.M., N.K., R.S., R.B., J.B., and V.W., a ratio of 2:10.

6. Outside of the written work schedule, there are no records to document the hours that managing pharmacist Assa Krutilin was present in the pharmacy.

CONCLUSIONS OF LAW

Based upon the foregoing findings of fact, the Board concludes as a matter of law:

7. As the managing pharmacist of Omnicare, Assa Krutilin allowed ratios of supervising pharmacists to technicians to be exceeded in violation of NRS 639.220, NAC 639.250(1), and (2), performed his duties in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210(4), (12), (15), and/or NRS 639.255.

8. Respondent Assa Krutilin failed to keep records to document his own hours worked in the pharmacy in violation of NAC 639.245(1), engaged in unprofessional conduct as

defined in NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210(4), (12), (15), and/or NRS 639.255.

ORDER

THEREFORE, BASED UPON THE FINDINGS OF FACTS, AND CONCLUSIONS OF LAW, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. This Order shall serve as a public reprimand regarding Respondent Assa Krutilin's duties and responsibilities as a registered pharmacist.

2. Respondent Assa Krutilin shall pay fines of One Thousand Three Hundred Dollars ($1,300) for violations of his duties as a registered/supervising pharmacist by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

3. Respondent Assa Krutilin shall pay for his portion of attorney's fees and investigative costs of Seven Hundred Forty-Nine Dollars ($749) by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

4. The expired and non-renewed certificate of registration of Respondent Assa Krutilin, RPH, Certificate of Registration No. 18266, is considered forfeited pursuant to NRS 639.180(6).

5. In the event that Respondent applies for registration, or for any other registration or certificate with the Board, he shall appear before the Board to answer questions and provide testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

6. This Order is a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r-2 and 45 CFR Part 60.

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7. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17 day of December, 2021.

Helen Park, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of December 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Uri Assa Krutilin, RPH
[redacted]
Las Vegas, NV[redacted]

Omnicare of Las Vegas
1525 E. Sunset Road Suite 16
Las Vegas, NV 89119

KRISTOPHER MANGOSING

FILED
OCT 11 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. OMNICARE OF LAS VEGAS, Pharmacy License No. PHC01949, URI ASSA KRUTILIN, RPH, Certificate of Registration No. 18266, Respondents.	CASE NO. 18-052-PH-S 18-052-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, R.Ph., in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Omnicare of Las Vegas ("Omnicare") held a Nevada Pharmacy License No. PHC01949; and Respondent Uri Assa Krutilin, RPh ("Assa Krutilin") held a Nevada Pharmacist Certificate of Registration No. 18266, all issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent Omnicare is a compounding pharmacy located on 1525 E. Sunset, #16, Las Vegas, Nevada.

3. Respondent Assa Krutilin is/was the managing pharmacist of Omnicare during the relevant timeframes.

4. On or about June 29, 2018, Board staff visited Omnicare at 8:00 a.m. Pharmacist L.T. was the only pharmacist present with eight (8) technicians.

5. Upon review of the work schedules, timeclock records, security door scan records, and sign in logs, the following violations were discovered:

a. On or about June 18, 2018, from 8:00 a.m. to 9:30 a.m., Pharmacist J.P. and L.T. were present with technicians J.F., F.B., W.M., D.R., M.R., J.B., and D.W., a ratio of 2:7.

b. On or about June 22, 2018, from 8:00 a.m. to 8:30 a.m., Pharmacists H.B. and L.T. were present with technicians J.F., F.B., K.F., M.E., A.D., C.F., and V.W., a ratio of 2:7.

c. On or about June 22, 2018, from 1:30 p.m. to 4:00 p.m., Pharmacists H.B. and Respondent Assa Krutilin were present with technicians F.B., K.F., L.K., A.D., N.K., N.P., J.B., and V.W., a ratio of 2:8.

d. On or about June 22, 2018, from 5:30 p.m. to 6:00 p.m., Pharmacists H.B. was present with technicians A.M., L.K., A.D., N.K., N.P., and V.W., a ratio of 1:6.

e. On or about June 22, 2018, from 6:30 p.m. to 8:00 p.m., Pharmacist J.P. was present with technicians A.M., L.K., N.K., N.P., and V.W., a ratio of 1:5.

f. On or about June 22, 2018, from 8:00 p.m. to 8:30 p.m., Pharmacist J.P. was present with technicians L.K., N.K., N.P., and V.W., a ratio of 1:4.

g. On or about June 25, 2018, from 8:00 a.m. to 8:30 a.m., Pharmacist L.T. was present with technicians J.F., A.M., K.F., A.D., M.R., and V.W., a ratio of 1:6.

h. On or about June 25, 2018, from 2:30 p.m. to 4:00 p.m., Respondent Assa Krutilin and Pharmacist J.P. were present with technicians F.B., K.F., M.R., N.P., V.W., R.B., J.B., and D.W., a ratio of 2:8.

i. On or about June 25, 2018, from 4:00 p.m. to 4:30 p.m., Respondent Assa Krutilin, Pharmacists B.K. and J.P. were present with technicians A.D., F.B., K.F., M.R., N.K., N.P., V.W., R.S., R.B., and D.W., a ratio of 3:10.

j. On or about June 25, 2018, from 4:30 p.m. to 5:00 p.m., Pharmacists B.K. and J.P. were present with technicians A.D., F.B., N.K., V.W., R.S., J.B., and R.B., a ratio of 2:7.

k. On or about June 29, 2018 at 8:00 a.m., Pharmacist L.T. was present with F.B., W.M., A.D., C.F., N.P., M.E., V.W., and J.B., a ratio of 1:8.

l. On or about June 29, 2018, from 4:00 p.m. to 4:30 p.m., Pharmacists H.B., and B.K. were present with technicians A.M., F.B., K.F., L.K., W.M., N.K., R.S., R.B., J.B., and V.W., a ratio of 2:10.

6. Outside of the written work schedule, there are no records to document the hours that managing pharmacist Assa Krutilin was present in the pharmacy.

APPLICABLE LAW

7. Each pharmacy must be managed by a registered pharmacist responsible for the compliance of the pharmacy and its personnel with all federal and state laws and regulations relating to the operation of the pharmacy. NRS 639.220.

8. A written record must be kept available for inspection showing the pharmacists, pharmaceutical technicians, and pharmaceutical technicians on duty during the hours of business. NAC 639.245(1).

9. A managing pharmacist is responsible for violations committed by the pharmacy's employees. NRS 639.220(1); NAC 639.702.

10. The Board may suspend or revoke a registration pursuant to NRS 639.210(15) when a person has "as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of this chapter or other state or federal laws or

regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision."

11. A pharmacy that requires or allows a pharmacist to use pharmaceutical technicians in violation of law or regulation is subject to discipline. NAC 639.260.

12. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NAC 639.702; NAC 639.945(2).

FIRST CAUSE OF ACTION
Violations of Law and Unprofessional Conduct
(Respondent Assa Krutilin)

13. As the managing pharmacist of Omnicare, Assa Krutilin allowed ratios of supervising pharmacists to technicians to be exceeded in violation of NRS 639.220, NAC 639.250(1), and (2), performed his duties in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210(4), (12), (15), and/or NRS 639.255.

14. Respondent Assa Krutilin failed to keep records to document his own hours worked in the pharmacy in violation of NAC 639.245(1), engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210(4), (12), (15), and/or NRS 639.255.

SECOND CAUSE OF ACTION
Pharmacy/Owner Responsibilities
(Respondent Omnicare)

15. As the owners/operators of Omnicare at the time of each of the violations alleged herein, Omnicare is responsible for the violations, including those of its employees, pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2), and is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255.

16. Omnicare allowed pharmacists to use pharmaceutical technicians in violation of ratios pursuant to NAC 639.260, and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license/registration of these Respondents.

Signed this 11th day of October 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board, and to submit an answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, then the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **URI ASSA KRUTILIN, RPH,** **Certificate of Registration No. 18266,** **Respondent.**	**CASE NO. 18-052-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The hearing for case number 18-052-RPH-S has been scheduled for Wednesday, December 1, 2021, 9:00 AM PST or soon thereafter. Pursuant to NRS 241.023(1)(c) you may appear live via Zoom remotely or at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd.
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671

or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of October, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **URI ASSA KRUTILIN, RPH,** **Certificate of Registration No. 18266,** **Respondent.**	**CASE NO. 18-052-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

URI ASSA KRUTILIN, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of October, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

URI ASSA KRUTILIN, RPH
[redacted]
LAS VEGAS, NV, [redacted]

OMNICARE OF LAS VEGAS
1525 E SUNSET ROAD SUITE 16
LAS VEGAS, NV 89119

SHIRLEY HUNTING

5B

FILED
JAN 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ERIC MARTIN MATH, MD,** **Certificate of Registration No. CS04598,** **Respondent.**	**CASE NO. 19-083-CS-N** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Eric Martin Math, MD, revoked Certificate of Registration No. CS04598, is hereby directed to appear before the Board for a hearing to show cause scheduled **for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

2. On April 21, 2022, the Board entered its Findings of Fact, Conclusions of Law, and Order revoking Certificate of Registration No. CS04598 and imposing discipline on Respondent pursuant to NRS 453.241(1)(b) and NRS 639.255 (Order).

3. Respondent has failed to make payment of a fine of Five Thousand Dollars ($5,000.00) pursuant to the Order.

4. Respondent has failed to make payment of Eight Hundred Twelve Dollars and Fifty Cents ($812.50) for attorney's fees and investigative costs pursuant to the Order.

5. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapters 453 and 639, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 17th day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of Jan. 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Eric M. Math, MD
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
APR 21 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. ERIC MARTIN MATH, MD, Certificate of Registration No. CS04598, Respondent.	CASE NO. 19-083-CS-N FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, April 14, 2021. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Eric Martin Math, MD, Certificate of Registration No. CS04598, appeared through counsel, Hal Taylor, Esq. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The allegations against Respondent, as stated in the Notice of Intended Action and Accusation (Accusation) on file herein, and upon which the Board makes findings of fact, are as follows:

1. At the time of the events herein, Respondent Eric Martin Math, MD, held a Nevada controlled substance registration, Certificate No. CS04598, issued by the Board.

2. On June 3, 2019, Respondent surrendered his DEA Certificate of Registration No. BM4705616 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

3. By executing the DEA Surrender for Cause, Respondent acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

4. On or about June 4, 2019, Board staff notified Respondent that his surrender of DEA Certificate of Registration No. BM4705616 for cause operated as an immediate suspension of his Certificate of Registration No. CS04598 with the Board pursuant to NRS 639.2107.

5. On or about June 27, 2019, Respondent requested that his License No. 8878 issued by the Nevada State Board of Medical Examiners (NSBME) be placed on inactive status pursuant to NRS 630.255 rather than renewed on the basis that he was not engaged in the practice of medicine in Nevada.

6. On or about July 12, 2019, Board Staff properly served Respondent with the Notice of Intended Action and Accusation on file in this matter together with the Statement to Respondent and Notice of Hearing.

7. On or about September 3, 2019, Respondent filed an Answer and Notice of Defense to the original Accusation and requested a stay of administrative proceedings until final disposition of *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026. Pursuant to NAC 639.120(1) this matter was continued.

8. On or about March 2, 2020, Respondent entered into a plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, wherein he pled guilty to one count of conspiracy to distribute a controlled substance – hydrocodone and oxycodone, in violation of 21 USC § 841(a)(1) and (b)(1)(c) and 21 USC § 846.

9. Board staff incurred at least $812.50 in attorney's fees prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and this respondent, because at the time of the events herein, Respondent was a practitioner registered with the Board.

2. The applicable law in this matter is as follows:

a. A practitioner must hold an active license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or dispense any controlled substance. NRS 453.226(1); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03.

b. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has been convicted of a felony under a state or federal law relating to a controlled substance. NRS 453.236(1)(b) and NRS 453.241(1).

c. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

d. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

e. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

f. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

g. The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

h. Conviction of a felony for a violation of federal law concerning drugs operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2121.

3. By violating the Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Respondent is subject to discipline and his Certificate of Registration No. CS04598 subject to revocation pursuant to NRS 453.236(1)(b) and NRS 639.210(11) and (12).

4. By violating the federal Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Respondent has committed acts that render his registration to dispense controlled substances inconsistent with the public interest pursuant to NRS 453.231, no longer qualifies for registration to dispense controlled substances under federal or state law, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

5. By violating the Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct

contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

6. By placing his NSBME License No. 8878 to practice medicine on inactive status, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law, and is subject to suspension pursuant to NRS 453.236(1) and NRS 453.241(1).

7. By surrendering his DEA Certificate of Registration No. BM4705616 for cause and by his felony conviction, Respondent has admitted to violating federal law, is no longer authorized by federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

8. The suspension of Respondent's Nevada Controlled Substance Registration, Certificate No. CS04598, pursuant to NRS 639.2107 and NRS 639.2121 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Eric Martin Math, MD, Certificate of Registration No. CS04598, is hereby revoked pursuant to NRS 453.241(l)(b).

2. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration.

3. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of five (5) years from the effective date of this Order.

4. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to

answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

5. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five-Thousand Dollars ($5,000.00) for the violations, by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order.

6. Pursuant to NRS 622.400, Respondent shall pay $812.50 to partially reimburse the Board for reasonable and necessary attorney's fees actually incurred in prosecuting this matter. Payment shall be made by *cashier's check, certified check* or *money order* made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

7. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 453 and/or NRS Chapter 639.

8. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 21st day of April, 2021.

Helen Park, President
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ERIC MARTIN MATH, MD,** **Certificate of Registration No.** CS04598, **Respondent.**	**CASE NO. 19-083-CS-N** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Eric Martin Math, MD (Math), held a Nevada Controlled Substance Registration, Certificate No. CS04598, issued by the Pharmacy Board.

FACTUAL ALLEGATIONS

2. On June 3, 2019, Math surrendered his DEA Certificate of Registration No. BM4705616 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

3. By executing the DEA Surrender for Cause, Math acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

NEVADA STATE BOARD OF PHARMACY
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4. On or about June 4, 2019, Board staff notified Math that his surrender of DEA Certificate of Registration No. BM4705616 for cause operated as an immediate suspension of his Certificate of Registration No. CS04598 with the Board pursuant to NRS 639.2107.

5. On or about June 27, 2019, Math requested that his License No. 8878 issued by the Nevada State Board of Medical Examiners (NSBME) be placed on inactive status pursuant to NRS 630.255 rather than renewed on the basis that he was not engaged in the practice of medicine in Nevada.

6. On or about July 12, 2019, Board Staff properly served Math with the Notice of Intended Action and Accusation on file in this matter together with the Statement to Respondent and Notice of Hearing.

7. On or about September 3, 2019, Math filed an Answer and Notice of Defense to the original Accusation and requested a stay of administrative proceedings until final disposition of *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026. Pursuant to NAC 639.120(1) this matter was continued.

8. On or about March 2, 2020, Math entered into a plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, wherein he pled guilty to one count of conspiracy to distribute a controlled substance – hydrocodone and oxycodone, in violation of 21 USC § 841(a)(1) and (b)(1)(c) and 21 USC § 846.

FIRST CAUSE OF ACTION
Violation of Federal Law

9. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has been convicted of a felony under a state or federal law relating to a controlled substance. NRS 453.236(1)(b) and NRS 453.241(1).

10. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

11. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

12. By violating the Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Math is subject to discipline and his Certificate of Registration No. CS04598 subject to revocation pursuant to NRS 453.236(1)(b) and NRS 639.210(11) and (12).

SECOND CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

14. By violating the federal Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Math has committed acts that render his registration to dispense controlled substances inconsistent with the public interest pursuant to NRS 453.231, no longer qualifies for registration to dispense controlled substances under federal or state law, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

THIRD CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

16. By violating the Controlled Substances Act, 21 U.S.C. Chap. 13, as detailed in the plea agreement in *United States vs. Myron Motley, Eric Math, MD, et al*, Case No. 3:19-cr-00026, Math has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

FOURTH CAUSE OF ACTION

Inactive License to Practice Medicine

17. A practitioner must hold an active license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or dispense any controlled substance. NRS 453.226(1); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03.

18. By placing his NSBME License No. 8878 to practice medicine on inactive status, Math no longer qualifies for registration to dispense controlled substances under federal or state law, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

FIFTH CAUSE OF ACTION

Surrender of DEA Registration for Cause and Federal Conviction

19. The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

Conviction of a felony for a violation of federal law concerning drugs operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2121.

20. By surrendering his DEA Certificate of Registration No. BM4705616 for cause and his felony conviction, Math has admitted to violating federal law, is no longer authorized by federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

21. The suspension of Math's Nevada Controlled Substance Registration, Certificate No. CS04598 pursuant to NRS 639.2107 and NRS 639.2121 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 16 day of January, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ERIC MARTIN MATH, MD,** **Certificate of Registration No. CS04598,** **Respondent.**	**CASE NO. 19-083-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, March 3, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 20th day of January, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
	)	
Petitioner,	)	
v.	)	**ANSWER AND NOTICE**
	)	**OF DEFENSE**
ERIC MARTIN MATH, MD,	)	
Certificate of Registration No. CS04598,	)	
	)	
Respondent.	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ___ day of _____, 2021.

_____

ERIC MARTIN MATH, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of January, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

David R. Houston, Esq.
432 Court Street
Reno, NV 89501

SHIRLEY HUNTING

FILED
JUL 12 2019
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
Petitioner,	)	
v.	)	
	)	**NOTICE OF INTENDED ACTION**
ERIC MARTIN MATH, MD,	)	**AND ACCUSATION**
Certificate of Registration No. CS04598,	)	
Respondent.	)	

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Eric Martin Math, MD (Math), held a Nevada Controlled Substance Registration, Certificate No. CS04598, issued by the Pharmacy Board.

FACTUAL ALLEGATIONS

II.

On June 3, 2019, Math surrendered his DEA Certificate of Registration No. BM4705616 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

III.

By executing the DEA Surrender for Cause, Math acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

IV.

On or about June 4, 2019, Board staff notified Math that his surrender of DEA Certificate of Registration No. BM4705616 for cause operated as an immediate suspension of his Certificate of Registration No. CS04598 with the Board pursuant to NRS 639.2107.

APPLICABLE LAW

V.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

VI.

The surrender of a registration to the Drug Enforcement Administration by a practitioner operates as an immediate suspension of a registration issued by the Board pursuant to NRS Chapter 453 to possess, administer, prescribe or dispense controlled substances. NRS 639.2107.

VII.

Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

VIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION

IX.

By failing to comply with the Federal requirements pertaining to controlled substances, Math committed an act that would render his Nevada Controlled Substance Registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

SECOND CAUSE OF ACTION

X.

By surrendering his DEA Certificate of Registration No. FM2307468 for cause, the suspension of Math's Nevada Controlled Substance Registration, Certificate No. CS04598 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

THIRD CAUSE OF ACTION

XI.

By failing to comply with the Federal requirements pertaining to controlled substances, Math is subject to discipline pursuant to NRS 639.210(11) and/or (12), and NRS 639.255.

XII.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 12th day of July, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-083-CS-N**
	)	
Petitioner,	)	
v.	)	
	)	**STATEMENT TO THE**
ERIC MARTIN MATH, MD,	)	**RESPONDENT**
Certificate of Registration No. CS04598,	)	**NOTICE OF INTENDED ACTION**
	)	**AND ACCUSATION**
Respondent.	/	**RIGHT TO HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, September 4, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 12th day of July, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Eric Math, MD
[redacted]
Reno, NV [redacted]

SHIRLEY HUNTING

RETURN OF SERVICE

STATE OF NEVADA)
ss.
COUNTY OF WASHOE)

I HEREBY certify and return that I received the within Notice of Intended Action, Statement to the Respondent Notice of Intended Action and Accusation Right to Hearing, Answer and Notice of Defense, and Suspension of Certificate of Registration No. CS04598 on the 31st day of July, 2019 and that I personally served the same upon Front desk receptionist Itzel Arnate at the law office of David Huston, 432 Court Street, Reno, NV 89501, a person at least eighteen years of age, at law office of David Huston on the 31st day of July, 2019.

Signature

Joseph J. Depczynski

Name (print)

SUBSCRIBED AND SIGNED before me

this 31st day of JULY, 2019

by JOSEPH J. DEPCZYNSKI

NOTARY PUBLIC

SHIRLEY LOWERY-HUNTING
Notary Public - State of Nevada
Appointment Recorded in Washoe County
No: 13-10953-2 - Expires May 24, 2021

FILED
APR 12 2021
NEVADA STATE BOARD OF PHARMACY

Hal Taylor, Esq.
SBN: 4399
1551 W. Lakeridge Shores.
Reno, NV 89519
Tel: (775) 825-2223
Fax: (775) 329-1113
Email: HalTaylorLawyer@gbis.com
Attorney for Eric Martin Math, MD

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY Petitioner, v. ERIC MARTIN MATH, MD Certificate of Registration No. CS04598, Respondent, /	Case No.: 19-083-CS-N

Amended Answer

Respondent Eric Martin Math, MD, through his counsel, Hal Taylor, Esq., responds to the Notice of Intended Action and Accusation ("Accusation") filed by the Nevada State Board of Pharmacy ("Board") as follows:

JURISDICTION

I.

Admitted.

INCORPORATION OF PREVIOUS ANSWER AND NOTICE OF DEFENSE

Respondent Math, though his criminal counsel, David R. Houston, Esq., previously filed an Answer and Notice of Defense ("Original Answer"). By this reference, the relevant portions of the Original Answer are incorporated into this Amended Answer as if fully set forth herein. It is anticipated that if a trial goes forward of the Co-Defendants in the Federal case against Respondent Math, that he may be subpoenaed to testify the United States Attorney's Office.

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HAL TAYLOR, ESQ.
2551 W. Lakeridge Shores
RENO, NV 89519
TEL. (775) 825-2225 - HalTaylorLawyer@gbis.com

FACTUAL ALLEGATIONS

II.

Since the filing of the Original Answer, Respondent Math entered into a Plea Agreement with the United States Attorney's Office in which he agreed to plead guilty to Count I of the indictment (Conspiracy to distribute a controlled substance - hydrocodone and oxycodone.) in *United States of America v Eric Math*, Case No.: 3:19-cr-0026 pending in the Untied States District Court for the District of Nevada "District Court"). That plea has been accepted by the District Court, and Respondent Math is waiting for sentencing, currently scheduled for June 15, 2021.

The relevant factual admissions are contained in Factual Basis portion of the Plea Agreement, incorporated by this reference into this Amended Answer.

Admitted that Respondent Math surrendered his DEA Certificate of Registration as alleged.

III.

Admitted as to statements made in the DEA Surrender for Cause.

IV.

Admitted.

APPLICABLE LAW

V.

Admitted.

VI.

Admitted.

VII.

Admitted.

VIII.

Admitted.

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HAL TAYLOR, ESQ.
2551 W. Lakeridge Shores
RENO, NV 89519
TEL. (775) 825-2225 - HalTaylorLawyer@gbis.com

FIRST CAUSE OF ACTION

IX.

Admitted that were the Board to find that Respondent Math failed to comply with the Federal requirements pertaining to controlled substances that Respondent Math may be subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.24(1).

SECOND CAUSE OF ACTION

X.

Admitted.

THIRD CAUSE OF ACTION

XI.

Admitted that were the Board to find that Respondent Math failed to comply with the Federal requirements pertaining to controlled substances that Respondent Math may be subject to discipline pursuant to NRS 639.210(11) and/or (12), and NRS 639.255.

XII.

Wherefore, Respondent Eric Math, M.D. prays that the Board will enter an order appropriate to this case which will allow Respondent Math to seek active licensure in the future under appropriate circumstances and conditions.

AFFIRMATION PURSUANT TO NRS 239B.030

By signature below, the undersigned affirms that the preceding document does not contain the social security number of any person.

Dated: April 12, 2021.

HAL TAYLOR, ESQ.
2551 W. Lakeridge Shores
Reno, Nevada 89519
(775) 825-2223

HAL TAYLOR
Attorney for Respondent

HAL TAYLOR, ESQ.
2551 W. Lakeridge Shores
RENO, NV 89519
TEL.: (775) 825-2225 - HalTaylorLawyer@gbls.com

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I certify that I am an employee of Hal Taylor, Attorney at Law, and that on this date, I electronically filed the foregoing **Amended Answer** with the Nevada State Board of Pharmacy.

Dated: April 12, 2021

Hal Taylor, Esq.

HAL TAYLOR, ESQ.
2551 W. Lakeridge Shores
RENO, NV 89519
TEL.. (775) 825-2225 - HalTaylorLawyer@gbis.com

ORIGINAL

FILED
SEP - 3 2019
NEVADA STATE BOARD OF PHARMACY

DAVID R. HOUSTON, ESQ.
Nevada Bar No. 2131
LAW OFFICE OF DAVID R. HOUSTON
A Professional Law Corporation
432 Court Street
Reno, Nevada 89501
Telephone: 775.786.4188
Facsimile: 775.786.5573
Attorney for Defendant

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. ERIC MATH, M.D. Certificate of Registration No. CS04598. Respondent, /	**CASE NO. 19-083-CS-N** **ANSWER AND NOTICE OF DEFENSE** **Date of Hearing: Sept. 4, 2019** **Time of Hearing: 9:00 a.m.**

Respondent, ERIC MATH, MD (hereinafter "Dr. Math"), by and through his attorney, DAVID R. HOUSTON, ESQ., of THE LAW OFFICE OF DAVID R. HOUSTON, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy declares:

1. That he is currently under indictment in the United States District Court for the District of Nevada in the case of United States of America vs. Myron Motley, Eric Math, M.D., Michael Kwoka, Michael Slater, Joseph Jeannette, Ivy Elliott, and Alesia Sampson, Case No.: 3:19-CR-00026-LRH-CBC (hereinafter "the federal case").
2. That the facts and circumstances alleged in the Nevada State Board of Pharmacy Notice of Intended Action and Accusation are the same or are substantially similar to the facts and circumstances alleged by the United States Attorney's Office in the federal case.
3. That providing any specific factual response to the Notice of Intended Action and Accusation would require Dr. Math to make statements that could be used against him in proceedings in the federal case.

4. The privilege against self-incrimination embodied in the Fifth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment to the United States Constitution, can be "claimed in any proceeding, be it criminal or civil, administrative or judicial, investigatory or adjudicatory... it protects any disclosures which the witness may reasonably apprehend could be used in a criminal prosecution or which could lead to other evidence that might be so used". In re Gault, 387 U.S. 1,47-48 (1967), quoting Murphy v. Waterfront Comm'n, 378 U.S. 52, 94 (1964) (emphasis added in original).

5. "[T]he availability of privilege does not turn upon the type of proceeding in which its protection is invoked, but upon the nature of the statement or admission and the exposure which it invites. The privilege may, for example, be claimed in a civil or administrative proceeding, if the statement is or may be inculpatory". In re Gault, 387 U.S. 1, 48 (1967) (emphasis added).

6. Dr. Math cannot be compelled to answer the specific allegations set forth in the Notice of Intended Action and Accusation.

7. Dr. Math's refusal to answer the allegations is in no way an admission of any of the allegations.

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REQUEST FOR STAY OF PROCEEDINGS

Based upon the foregoing, Dr. Math hereby requests that the proceedings in the Nevada State Board of Pharmacy be stayed until such time as the federal case is resolved. Dr. Math understands that his Certificate of Registration No. CS04598 with the Nevada State Board of Pharmacy is suspended until the allegations set forth in the Accusation are fully addressed and adjudicated by the Board.

DATED this 3rd day of September 2019.

David R. Houston, Esq.

432 Court Street
Address

Reno, Nevada
City, State

89501 775-786-4188
Zip Code Telephone

CERTIFICATE OF SERVICE

The undersigned does hereby affirm that I am an Employee of the Law Office of David R. Houston and that on this date, I caused to be delivered via hand delivery a true and correct copy of the within document, to the below-named:

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

DATED this 3rd day of September 2019.

Crystal Guardino

U. S. Department of Justice - Drug Enforcement Administration

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY

File No. [redacted]

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
Eric Martin Math, M.D.	5538 Longley Ln. Ste B Reno, NV 89511
DEA REGISTRATION NO.	
BM4705616	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE
[signature]	6/3/19

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
[signature] 6/3/19	Special Agent
NAME AND DATE	TITLE
[signature] 6/3/19	Special Agent

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.

FORM DEA-104 (07/18) *Previous editions obsolete*

✓ FILED
ENTERED
RECEIVED
SERVED ON
COUNSEL/PARTIES OF RECORD
MAR - 2 2020
CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: _____ DEPUTY

NICHOLAS A. TRUTANICH
United States Attorney
District of Nevada
Nevada Bar Number 13644
ROBERT A. KNIEF
Assistant United States Attorney
501 Las Vegas Boulevard South, Suite 1100
Las Vegas, Nevada 89101
Telephone: (702) 388-6336
Email: Robert.Knief@usdoj.gov
Counsel for Plaintiff United States

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. ERIC MATH, Defendant.	No. 3:19-cr-0026-LRH-WGC **Plea Agreement Pursuant to Fed. R. Crim. P. 11(c)(1)(A) and (B)**

This plea agreement between Eric Math ("defendant") and the United States Attorney's Office for the District of Nevada (the "USAO") sets forth the parties' agreement regarding the criminal charges referenced herein and the applicable sentences, in the above-captioned case. This agreement binds only defendant and the USAO and does not bind the district court, the U.S. Probation Office, or any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authorities. This agreement does not prohibit the USAO or any agency or third party from seeking any other civil or administrative remedies, including civil forfeiture *in rem,* directly or indirectly against defendant or defendant's property.

This agreement becomes effective upon signature by defendant, defendant's counsel, and an Assistant United States Attorney

I. DEFENDANT'S OBLIGATIONS

1. Defendant agrees to:

a. At the earliest opportunity requested by the USAO and provided by the district court, appear and plead guilty to Count 1 of the indictment in this case, which charges defendant with conspiracy to distribute a controlled substance – hydrocodone, and oxycodone in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 846 (Count Two);

b. Stipulate to the facts agreed to in this agreement;

c. Abide by all agreements regarding sentencing contained in this agreement;

d. Not seek to withdraw defendant's guilty plea once it is entered;

e. Appear for all court appearances, surrender as ordered for service of sentence, obey all conditions of any bond, and obey any other ongoing court order in this matter;

f. Not commit any federal, state, or local crime;

g. Be truthful at all times with the U.S. Probation and Pretrial Services Offices and the Court;

II. THE USAO'S OBLIGATIONS

2. The USAO agrees to:

a. Stipulate to facts agreed to in this agreement;

b. Abide by all agreements regarding sentencing contained in this agreement;

c. At sentencing, provided that defendant demonstrates an acceptance of responsibility for the offense up to and including the time of sentencing, recommend a two-level reduction in the applicable sentencing guidelines offense level, pursuant to USSG § 3E1.1, and move for an additional one-level reduction if available under that section;

d. At sentencing, move to dismiss the remaining counts of the indictment as against defendant. Defendant agrees, however, that the district court may consider any dismissed

charges in determining the applicable sentencing guidelines range, the propriety and extent of any departure from that range, and the sentence to be imposed.

III. ELEMENTS OF THE OFFENSE

3. Count One: The elements of conspiracy to distribute a controlled substance – hydrocodone, and oxycodone in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 846 are as follows:

First: Beginning at a time unknown, but not later than on or about October 21, 2018, and continuing to on or about May 23, 2019, there was an agreement between two or more persons to unlawfully possess with intent to distribute oxycodone, a schedule II controlled substance; and

Second: The defendant joined in the agreement knowing of its purpose and intending to help accomplish that purpose.

Ninth Circuit Model Criminal Jury Instr. 9.19.

IV. CONSEQUENCES OF CONVICTION

4. Maximum Statutory Penalties:

Defendant understands that the statutory maximum sentence the district court can impose for a violation of 21 U.S.C. §§ 841(a)(1), 841(b)(1)(C), and 846 as charged in Count 1, is: 20 years imprisonment; a minimum of five years and up to lifetime supervised release a fine of $250,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of #$100.

5. Defendant understands that under 21 U.S.C. § 862a, defendant will not be eligible for assistance under state programs funded under the Social Security Act or Federal Food Stamp Act or for federal food stamp program benefits, and that any such benefits or assistance received by defendant's family members will be reduced to reflect defendant's ineligibility.

6. Parole Abolished: Defendant acknowledges that defendant's prison sentence cannot be shortened by early release on parole because parole has been abolished.

7. Supervised Release: Defendant understands that supervised release is a period of time following imprisonment during which defendant will be subject to various restrictions and requirements. Defendant understands that if defendant violates one or more of the conditions of any supervised release imposed, defendant may be returned to prison for all or part of the term of supervised release authorized by statute for the offense that resulted in the term of supervised release.

8. Factors under 18 U.S.C. § 3553: Defendant understands that the district court must consider the factors set forth in 18 U.S.C. § 3553(a) in determining defendant's sentence. However, the statutory maximum sentence limits the district court's discretion in determining defendant's sentence.

9. Potential Collateral Consequences of Conviction: Defendant understands that, by pleading guilty, defendant may be giving up valuable government benefits and valuable civic rights, such as the right to vote, the right to possess a firearm, the right to hold office, and the right to serve on a jury. Defendant understands that once the district court accepts defendant's guilty plea, it will be a federal felony for defendant to possess a firearm or ammunition. Defendant understands that the conviction in this case may also subject defendant to various other collateral consequences, including but not limited to revocation of probation, parole, or supervised release in another case and suspension or revocation of a professional license. Defendant understands that unanticipated collateral consequences will not serve as grounds to withdraw defendant's guilty plea.

10. Potential Removal/Deportation Consequences of Conviction: Defendant understands that, if defendant is not a United States citizen, the felony conviction in this case

may subject defendant to removal, also known as deportation, which may, under some circumstances, be mandatory; denial of citizenship; and denial of admission to the United States in the future. The district court cannot, and defendant's attorney also may not be able to, advise defendant fully regarding the immigration consequences of the felony conviction in this case. Defendant understands that unexpected immigration consequences will not serve as grounds to withdraw defendant's guilty plea.

V. FACTUAL BASIS

11. Defendant admits that defendant is, in fact, guilty of the offense to which defendant is agreeing to plead guilty. Defendant acknowledges that if defendant elected to go to trial instead of pleading guilty, the USAO could prove defendant's guilt beyond a reasonable doubt. Defendant further acknowledges that defendant's admissions and declarations of fact set forth below satisfy every element of the charged offense. Defendant waives any potential future claim that the facts defendant admitted below are insufficient to satisfy the elements of the charged offense. Defendant admits and declares under penalty of perjury that the facts set forth below are true and correct:

Between about October 21, 2018, and continuing to on or about May 23, 2019, I entered into an agreement with Myron Motley, Joe Jeannette, and others. We agreed to distribute controlled substances, specifically oxycodone and hydrocodone. I would write prescriptions to my co-conspirators not for a legitimate medical purpose and not in the usual course of professional practice. They would fill the prescriptions and give some of this pills to Motley for further sales. Sometimes I would be paid in cash for writing the prescriptions and sometimes I would write prescriptions for myself and have the co-conspirator fill the prescription and I would recive the pills.

I joined in the agreement knowing its purpose was unlawful and with the intent to help accomplish that purpose. This actiovity ocurred in the State and Federal District of Nevada.

VI. SENTENCING FACTORS

12. Discretionary Nature of Sentencing Guidelines: Defendant understands that in determining defendant's sentence, the district court is required to calculate the applicable sentencing guidelines range and to consider that range, possible departures under the sentencing guidelines, and the other sentencing factors set forth in 18 U.S.C. § 3553(a). Defendant understands that the sentencing guidelines are advisory only, that defendant cannot have any expectation of receiving a sentence within the calculated sentencing guidelines range, and that after considering the sentencing guidelines and the other § 3553(a) factors, the district court will be free to exercise its discretion to impose any sentence it finds appropriate.

13. Offense Level Calculations: The parties jointly agree and stipulate that, in calculating Defendant's advisory guidelines sentencing range, the Court should use the following base offense level and adjustments; acknowledge that these stipulations do not bind the district court:

Base Offense Level - USSG § 2D1.1(c)(5):	30
Abuse of Trust - USSG § 3B1.3:	+2
Adjusted Offense Level:	32

14. Agreement with Respect to Some Safety Valve Requirements: Defendant and the USAO agree that:

a. Defendant did not use violence or credible threats of violence or possess a firearm or other dangerous weapon (or induce another participant to do so) in connection with the offense charged in count 1;

b. The offense charged in count 1 did not result in death or serious bodily injury to any person; and

c. Defendant was not an organizer, leader, manager, or supervisor of others in the offense charged in count 1 and was not engaged in a continuing criminal enterprise.

d. Defendant and the USAO have made no agreement whether defendant qualifies for safety-valve relief from the statutory minimum sentence, and Defendant agrees that, if the district court determines he does not qualify, that determination will not serve as grounds to withdraw defendant's guilty plea.

15. Reduction for Acceptance of Responsibility: Under USSG § 3E1.1(a), the USAO will recommend that defendant receive a two-level downward adjustment for acceptance of responsibility unless defendant (a) fails to truthfully admit facts establishing a factual basis for the guilty plea when defendant enters the plea; (b) fails to truthfully admit facts establishing the amount of restitution owed when defendant enters the guilty plea; (c) fails to truthfully admit facts establishing the forfeiture allegations when defendant enters the guilty plea; (d) provides false or misleading information to the USAO, the Court, Pretrial Services, or the Probation Office; (e) denies involvement in the offense or provides conflicting statements regarding defendant's involvement or falsely denies or frivolously contests conduct relevant to the offense; (f) attempts to withdraw defendant's guilty plea; (g) commits or attempts to commit any crime; (h) fails to appear in court; or (i) violates the conditions of pretrial release.

Under USSG § 3E1.1(b), if the district court determines that defendant's total offense level before operation of § 3E1.1(a) is 16 or higher, and if the USAO recommends a two-level downward adjustment pursuant to the preceding paragraph, the USAO will move for an additional one-level downward adjustment for acceptance of responsibility before sentencing

because defendant communicated defendant's decision to plead guilty in a timely manner that enabled the USAO to avoid preparing for trial and to efficiently allocate its resources.

16. Criminal History Category. Defendant acknowledges that the district court may base defendant's sentence in part on defendant's criminal record or criminal history. The district court will determine defendant's criminal history category under the sentencing guidelines.

17. Additional Sentencing Information: The stipulated sentencing guidelines calculations are based on information now known to the parties. Defendant understands that both defendant and the USAO are free to (a) supplement the facts in this agreement by supplying relevant information to the U.S. Probation and Pretrial Services Offices and the district court regarding the nature, scope, and extent of defendant's criminal conduct and any aggravating or mitigating facts or circumstances; and (b) correct any and all factual misstatements relating to the district court's sentencing guidelines calculations and determination of sentence. While this paragraph permits both the USAO and defendant to submit full and complete factual information to the U.S. Probation and Pretrial Services Offices and the district court, even if that factual information may be viewed as inconsistent with the facts agreed to in this agreement, this paragraph does not affect defendant's and the USAO's obligations not to contest the facts agreed to in this agreement. Good faith efforts to provide truthful information or to correct factual misstatements shall not be grounds for defendant to withdraw defendant's guilty plea.

Defendant acknowledges that the U.S. Probation Office may calculate the sentencing guidelines differently and may rely on additional information it obtains through its investigation. Defendant also acknowledges that the district court may rely on this and other additional information as it calculates the sentencing guidelines range and makes other sentencing determinations, and the district court's reliance on such information shall not be grounds for defendant to withdraw defendant's guilty plea.

VII. POSITIONS REGARDING SENTENCING

18. The USAO will recommend that the district court sentence defendant at the low end of the advisory guideline range as determined by the district court. Defendant may argue for a downward variance pursuant to 18 U.S.C. § 3553. Defendant acknowledges that the district court does not have to follow the recommendation of either party.

19. Notwithstanding its agreement to recommend a sentence as described above, the USAO reserves its right to defend any lawfully imposed sentence on appeal or in any post-conviction litigation.

20. If defendant commits any act that results in the Court finding that defendant is not entitled to a downward adjustment for acceptance of responsibility, the USAO is entitled to argue for any sentence it deems appropriate under 18 U.S.C. § 3553(a). In any such event, Defendant remains bound by the provisions of this agreement and shall not have the right to withdraw defendant's guilty plea.

VIII. WAIVER OF CONSTITUTIONAL RIGHTS

21. Defendant understands that by pleading guilty, defendant gives up the following rights:

a. The right to persist in a plea of not guilty;

b. The right to a speedy and public trial by jury;

c. The right to be represented by counsel—and if necessary have the court appoint counsel—at trial. Defendant understands, however, that, defendant retains the right to be represented by counsel—and if necessary have the court appoint counsel—at every other stage of the proceeding;

d. The right to be presumed innocent and to have the burden of proof placed on the USAO to prove defendant guilty beyond a reasonable doubt;

e. The right to confront and cross-examine witnesses against defendant;

f. The right to testify and to present evidence in opposition to the charges, including the right to compel the attendance of witnesses to testify;

g. The right not to be compelled to testify, and, if defendant chose not to testify or present evidence, to have that choice not be used against defendant; and

h. The right to pursue any affirmative defenses, Fourth Amendment or Fifth Amendment claims, and any other pretrial motions that have been filed or could be filed.

IX. WAIVER OF APPELLATE RIGHTS

22. Waiver of Appellate Rights. Defendant knowingly and expressly waives: (a) the right to appeal any sentence imposed within or below the applicable Sentencing Guideline range as determined by the district court; (b) the right to appeal the manner in which the district court determined that sentence on the grounds set forth in 18 U.S.C. § 3742.

23. Defendant reserves only the right to appeal any portion of the sentence that is an upward departure or variance from the applicable Sentencing Guideline range as determined by the district court.

24. Waiver of Post-Conviction Rights. Defendant also knowingly and expressly waives all collateral challenges, including any claims under 28 U.S.C. § 2255, to defendant's conviction, sentence, and the procedure by which the district court adjudicated guilt and imposed sentence, except non-waivable claims of ineffective assistance of counsel.

25. Preservation of Evidence: Defendant acknowledges that the USAO and the agencies investigating this case are not obligated or required to preserve any evidence obtained in the investigation of this case.

X. RESULT OF WITHDRAWAL OF GUILTY PLEA OR VACATUR/REVERSAL/SET-ASIDE OF CONVICTIONS

26. Consequence of withdrawal of guilty plea: Defendant agrees that if, after entering a guilty plea pursuant to this agreement, defendant seeks to withdraw and succeeds in withdrawing defendant's guilty plea on any basis other than a claim and finding that entry into this agreement was involuntary, then the USAO will be relieved of all of its obligations under this agreement.

27. Consequence of vacatur, reversal, or set-aside: Defendant agrees that if defendant's conviction is vacated, reversed, or set aside, both the USAO and defendant will be released from all their obligations under this agreement, except that, should the USAO choose to pursue any charge that was either dismissed or not filed as a result of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

XII. BREACH OF AGREEMENT

28. Defendant agrees that if, at any time after this agreement becomes effective, defendant knowingly violates or fails to perform any of defendant's obligations under this agreement ("a breach"), the USAO may declare this agreement breached. All of defendant's obligations are material, a single breach of this agreement is sufficient for the USAO to declare a breach, and defendant shall not be deemed to have cured a breach without the express agreement of the USAO in writing. If the USAO declares this agreement breached, and the district court finds such a breach to have occurred, then: (a) if defendant has previously entered a guilty plea

pursuant to this agreement, defendant will remain bound by the provisions of this agreement and will not be able to withdraw the guilty plea, and (b) the USAO will be relieved of all its obligations under this agreement.

XIII. COURT AND UNITED STATES PROBATION AND PRETRIAL SERVICES OFFICE NOT PARTIES.

29. Defendant understands that the Court and the U.S. Probation and Pretrial Services Office are not parties to this agreement and need not accept any of the USAO's sentencing recommendations or the parties' agreements to facts or sentencing factors.

30. Defendant understands that both defendant and the USAO are free to argue on appeal and collateral review that the district court's sentencing guidelines calculations and the sentence it chooses to impose are not error.

31. Defendant understands that even if the district court ignores any sentencing recommendation, finds facts or reaches conclusions different from those agreed to by the parties, or imposes any sentence up to the maximum established by statute, defendant cannot, for that reason, withdraw defendant's guilty plea, and defendant will remain bound to fulfill all defendant's obligations under this agreement. Defendant understands that no one—not the prosecutor, defendant's attorney, or the Court—can make a binding prediction or promise regarding the sentence defendant will receive, except that it will be within the statutory maximum.

XIV. ADDITIONAL ACKNOWLEDGMENTS

32. The Defendant acknowledges that:

a. Defendant read this agreement and defendant understands its terms and conditions.

b. Defendant had adequate time to discuss this case, the evidence, and this agreement with defendant's attorney.

c. Defendant carefully and thoroughly discussed all terms of this agreement with defendant's attorney.

d. Defendant understands the terms of this agreement and voluntarily agrees to those terms.

e. Defendant has discussed with defendant's attorney the following: the evidence; defendant's rights; possible pretrial motions that might be filed; possible defenses that might be asserted either prior to or at trial; the sentencing factors set forth in 18 U.S.C. 3553(a); the relevant sentencing guidelines provisions; and consequences of entering into this agreement.

f. The representations contained in this agreement are true and correct, including the factual basis for defendant's offense set forth in this agreement.

g. Defendant was not under the influence of any alcohol, drug, or medicine that would impair defendant's ability to understand the agreement when defendant considered signing this agreement and when defendant signed it.

33. Defendant understands that defendant alone decides whether to plead guilty or go to trial, and acknowledges that defendant has decided to enter defendant's guilty plea knowing of the charges brought against defendant, defendant's possible defenses, and the benefits and possible detriments of proceeding to trial.

34. Defendant understands that no promises, understandings, or agreements other than those set forth in this agreement have been made or implied by defendant, defendant's attorney, or the USAO, and no additional promises, agreements, or conditions shall have any force or effect unless set forth in writing and signed by all parties or confirmed on the record before the district court.

35. Defendant acknowledges that defendant decided to plead guilty voluntarily and that no one threatened, coerced, or forced defendant to enter into this agreement.

36. Defendant is satisfied with the representation of defendant's attorney, and defendant is pleading guilty because defendant is guilty of the charges and chooses to take advantage of the promises set forth in this agreement and for no other reason.

XV. PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING

37. The parties agree that this agreement will be considered part of the record of defendant's guilty plea hearing as if the entire agreement had been read into the record of the proceeding.

AGREED AND ACCEPTED

UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF NEVADA

NICHOLAS A. TRUTANICH
United States Attorney

/pHW — 3/2/20

ROBERT KNIEF
Assistant United States Attorney — Date

2/12/20

ERIC MATH
Defendant — Date

2-13-20

DAVID R. HOUSTON
Attorney for Defendant — Date

5C

FILED
FEB 2 8 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563 (McGuff Pharmacy), located in Santa Ana, California, was a pharmacy licensed by the Board, and McGuff Company, Inc, Wholesale License No. WH01300 (McGuff Company), located in Santa Ana, California, was a medical products wholesale distributor licensed by the Board.

FACTUAL ALLEGATIONS

2. McGuff Pharmacy and McGuff Company are both owned by Ronald M. McGuff.

3. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. §

262, Cal. Business and Professions Code § 4000 *et seq.*, and Cal. Code of Regulations, Title 16, Section 1700 *et seq.* (SEE EXHBIT A HERETO).

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications. *See also* 42 U.S.C. § 262 (regulation of biological products).

5. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

8. Respondents, their owner, and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a,

42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondents are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses of these Respondents.

Signed this 28th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

January 30, 2023

CERTIFIED MAIL

McGuff Compounding Pharmacy Services Inc.
Attn: Ronald McGuff, President
2921 W. MacArthur Blvd, Suite 142
Santa Ana, CA 92704

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

Dear Mr. McGuff:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order regarding the above-referenced matter. Your attention is directed to pages 4 - 8 of the document.

Effective at 5:00 p.m. on March 1, 2023, Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., is hereby surrendered and accepted by the Board and subject to the terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, Administrative Case Analyst, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

Enclosure(s)
cc: Desiree I. Kellogg, DAG
Joshua A. Room, SDAG
Tony J. Park, Pharm.D., J.D.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McGuff Compounding Pharmacy Services Inc. Attn: Ronald McGuff, President 2921 W. MacArthur Blvd, Suite 142 Santa Ana, CA 92704	7013 2630 0001 5115 0571
Tony J. Park, Pharm.D., J.D. California Pharmacy Lawyers 9090 Irvine Center Drive Irvine, CA 92618-6713	7013 2630 0001 5115 0595

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on January 30, 2023, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 30, 2023, at Sacramento, California.

Susan Cappello, Enforcement Manager

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER

Pharmacy Permit No. PHY 43950
Sterile Compounding License No. LSC 99004,

and

SI VAN PHAM

Pharmacist License No. RPH 49833

Respondents.

Agency Case No. 7176

OAH No. 2021120276

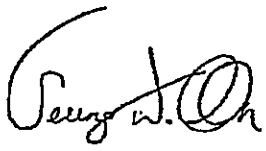
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2023.

It is so ORDERED on January 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 OAH No. 2021120276 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation with respect to Respondents McGuff Compounding Pharmacy Services Inc. and Si Van Pham.

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General, and Joshua A. Room, Supervising Deputy Attorney General.

2. Respondents are represented in this proceeding by attorney Tony J. Park, Pharm.D., J..D., whose address is: California Pharmacy Lawyers, Law Offices of Tony J. Park, Inc., 9090 Irvine Center Drive, Irvine, CA 92618, telephone (949) 336-7854.

3. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc. Ronald M. McGuff has served or been listed in Board records as the sole shareholder and President, Vice-President, and Secretary of McGuff Compounding Pharmacy Services Inc. (Respondent McGuff Compounding aka MCPS). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to Respondent McGuff Compounding aka MCPS. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

5. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Respondent Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed. Respondent Pham has served and been listed in Board records as Pharmacist-in-Charge of Respondent McGuff Compounding aka MCPS since July 9, 2016.

JURISDICTION

6. Accusation No. 7176 was filed before the Board, against Respondents. Accusation No. 7176 and all other statutorily required documents were properly served on Respondents on October 28, 2021. Respondents timely filed their Notice(s) of Defense contesting the Accusation. First Amended Accusation No. 7176 was filed before the Board, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on April 21, 2022. A copy of First Amended Accusation No. 7176 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 7176. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order on their respective permits and licenses.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel attendance of witnesses and production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 7176, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit, Sterile Compounding License, and Pharmacist License. For the purposes of resolving this matter without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for charges in the First Amended Accusation, and Respondents hereby give up their right to contest those charges.

11. Respondents agree that their Pharmacy Permit, Sterile Compounding License, and Pharmacist License are each and severally subject to discipline and they agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

DESIRED LICENSE CATEGORY TRANSITION

12. Respondent MCPS has decided to seek a transition from being a licensed pharmacy engaged in compounding (a Section 503A facility under federal law) to being a registered and licensed outsourcing facility (a Section 503B facility under federal law). This will entail an application to the Food and Drug Administration (FDA) for registration under Section 503B as an outsourcing facility, and then an application to the Board to be licensed in California as an outsourcing facility. It could take some significant time for MCPS to prepare for and make these applications. In the interim, the MCPS facility will cease functioning as a pharmacy on the effective date of the Decision and Order by the Board of Pharmacy adopting this stipulation.

13. This settlement of the First Amended Accusation does not depend on whether MCPS, any successor or assign thereof, or any entity sharing ownership or management with MCPS, actually submits a subsequent application to the Board for licensure as an outsourcing facility. In the event such application is submitted, the Board will give it the same consideration it would any other application to be licensed as an outsourcing facility. This settlement does not preclude the Board from granting that license. Nor is the Board under any obligation from this settlement to grant that license. Any such application will receive ordinary and fair consideration for licensure. If such an outsourcing facility license is granted, there is one term below that will be applied by the Board to that license, and which Respondent MCPS acknowledges will apply to itself, any successor or assign, or any entity sharing ownership or management with Respondent MCPS.

IMMEDIATE CEASE AND DESIST

14. As of the last date of all signatures on this Stipulated Settlement and Disciplinary Order, both Respondents agree to voluntarily and completely cease and desist compounding, or sales or transfers of compounded preparations, using any active ingredients or drug products named or identified in First Amended Accusation No. 7176, or any other active ingredient or drug product that is not graded for pharmaceutical use.

15. Any compounding by Respondents, or sales or transfers of compounded preparations, using such active ingredients or drug products after that date shall constitute unprofessional conduct and further cause for discipline by both Respondents, and may be considered by the Board in deciding whether to grant or deny any subsequent application by Respondent MCPS, its successor or assign, or any entity sharing ownership or management with Respondent MCPS, including but not limited to a subsequent application for an outsourcing facility license.

CONTINGENCY

16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

17. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

18. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

19. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

AS TO RESPONDENT MCGUFF COMPOUNDING AKA MCPS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43950, and Sterile Compounding License No. LSC 99004, both issued to Respondent McGuff Compounding aka MCPS, are each and severally surrendered and accepted by the Board.

20. **Definition: Respondent**

For the purposes of paragraphs 20-33, "Respondent" shall refer to Respondent McGuff Compounding aka MCPS. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

21. The surrender of Respondent's Pharmacy Permit and Sterile Compounding License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

22. Respondent shall lose all rights and privileges as a pharmacy and to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

23. Respondent shall be jointly and severally liable to the Board, along with Respondent Pham, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order.

24. Within (5) business days of the date this Stipulated Settlement and Disciplinary Order is fully executed, Respondent shall submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board. Any transfers of drug inventory shall be conducted in compliance with state and federal law.

25. If permitted by state and federal law, Respondent may transfer current inventory to its commonly-owned facilities as necessary to prepare for testing and other requirements to establish subsequent eligibility for an outsourcing facility registration and/or license.

26. Respondent shall cause to be delivered to the Board its pocket license and, if any were issued, its wall certificates, on or before the effective date of the Decision and Order.

27. Respondent shall also, by the effective date of the Decision and Order, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of its written notice to the Board. For purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

28. Respondent shall also, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

29. Neither Respondent nor its successor or assign, nor any entity sharing ownership or management with Respondent, shall apply to the Board for any permit, license, or registration issued by the Board for a period of three (3) years, except that at any time it is eligible for same:

- Respondent may submit an application for an outsourcing facility license;
- Respondent may apply for a change of location for its wholesaler license (WLS 2947), so long as there is no change in ownership or management structure, or any other substantive change aside from the change in location; and
- Should the Board change the name or category of licensure applicable to the WLS license, Respondent may apply to adopt this change, so long as there is no change in ownership or management structure, or other substantive change.

30. If Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, ever applies for licensure, including as an outsourcing facility, or petitions for reinstatement, the Board shall treat it as a new application for licensure. The applicant/petitioner must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and charges and allegations in First Amended Accusation No. 7176 shall be deemed to be supported by a factual basis and not contested by Respondent when the Board determines whether to grant or deny the application or petition.

31. If an application for an outsourcing facility license is submitted by Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, the Board may in addition consider, in deciding whether to grant or deny that license: whether Respondent met its agreement for the pharmacy to cease and desist compounding, sales, or transfers of drug preparations using active ingredients or drug products named or identified in First Amended Accusation No. 7176, or that are not graded for pharmaceutical use; and whether the Board has received full payment of the costs of investigation and enforcement in this case.

32. If an outsourcing facility license is granted by the Board to Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, that applicant/licensee shall retain, at its own expense, for a period of one (1) year after licensure, an independent consultant for the outsourcing facility approved in advance by the Board or its designee.

33. That independent consultant shall be a pharmacist licensed in good standing by the Board, and shall be responsible for conducting in-person inspections to review the operations of the outsourcing facility on a monthly basis for compliance with applicable state and federal laws. The independent consultant shall prepare and submit written reports directly to Board staff; such reports shall not go first to or be made available to the licensee by the independent consultant.

AS TO RESPONDENT PHAM

IT IS HEREBY ORDERED that Pharmacist License No. RPH 49833, issued to Respondent Pham, is revoked. However, the revocation is stayed and Respondent Pham is placed on probation for thirty-five (35) months on the following terms and conditions:

34. **Definition: Respondent**

For the purposes of paragraphs 34-52, "Respondent" shall refer to Respondent Pham.

35. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

36. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

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37. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

38. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

39. **Cooperate with Board Staff**

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

40. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current pharmacist license with the Board, including any period during which probation is tolled. Failure to maintain an active, current pharmacist license shall be considered a violation of probation.

If Respondent's pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

41. **Submission of Letter to Board**

Respondent shall, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make

whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

42. **Reimbursement of Board Costs**

Respondent shall be jointly and severally liable to the Board, along with Respondent MCPS, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order. It shall be a condition precedent to successful completion of probation that these costs were timely paid. Failure to pay costs by the deadline shall also be considered a violation of probation.

43. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

44. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in

California for the minimum of one hundred (100) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

45. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll, at Respondent's expense, in a course in ethics approved in advance by the Board or its designee, that complies with California Code of Regulations, title 16, section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

46. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90) days of the effective date of this decision and provide written proof thereof to the Board.

Failure to timely divest any legal or beneficial interest(s) or to immediately provide documentation thereof to the Board shall be considered a violation of probation.

47. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in name, residence or mailing address, email address, or phone number, shall be considered a violation of probation.

48. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7176 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each employer(s), and the name(s) and telephone number(s) of all direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s), and Respondent's work schedule, if known. Respondent shall also include reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee concerning Respondent's work status, performance, and monitoring.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his (a) direct supervisor, (b) pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7176, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Roard in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby.

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If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 7176, and the terms and conditions imposed thereby, in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s), or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board, shall be considered a violation of probation. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor, or volunteer.

49. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if Respondent or that entity retains, at his/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a monthly basis for compliance by Respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Respondent with the obligations of his supervisory position, for the duration of Respondent's probation period.

Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

50. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his pharmacist license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender will constitute a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

51. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____
Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/14/22

Ronald M. McGuff

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK, PHARM.D., J.D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

DESIREE L. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J.D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-14-22

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/14/2022

TONY J. PARK, PHARM.D., J.D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 14, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

/s/ Desiree I. Kellogg

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc., Ronald M. McGuff, sole shareholder and President, Vice-President and Secretary and Si Pham, Pharmacist-in-Charge since July 9, 2016 (McGuff Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

3. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to McGuff Compounding Pharmacy Services Inc. (MCPS). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Si Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed.

JURISDICTION

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq.*) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq.*).

7. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license

by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. Code section 4113, subdivision (c) states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Code section 4115, subdivision (a) states:

A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

13. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or re-packaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

///

14. Code section 4127.1, subdivisions (e)(3) and (f) state:

(e)(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

15. Code section 4127.8, subdivision (a) states:

A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

16. Section 4169 subdivision (a)(2) of the Code state:

(a) A person or entity shall not do any of the following:

...

(2) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

17. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

...

18. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

...

19. Code section 4307, subdivision (a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) states:

A drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

25. California Code of Regulations, title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

26. California Code of Regulations, title 16, section 1735.2, subdivisions (e), (g) and (h) state:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

...

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength.

27. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F) states:

For each compounded drug preparation, pharmacy records shall include: A compounding log consisting of a single document containing all of the following: the manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

28. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency,

quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

29. California Code of Regulations, title 16, section 1735.8, subdivision (a) states:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

30. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable).

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

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31. California Code of Regulations, title 16, section 1751.4, subdivision (f) states:

Pharmacies preparing-g sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

COST RECOVERY

32. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

33. Hydrogen peroxide infusions may be used to treat inflammation, are not Food and Drug Administration (FDA) approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

34. Dimercapto-propane sulfonic acid (DMPS) infusions may be used to treat mercury and other metal poisoning, are not FDA approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

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35. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

36. Lipoic acid infusions may be used to treat nerve pain, are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

37. Methylcobalamin infusions may be used to treat neurological conditions and pain, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

38. Disodium nicotinamide adenine dinucleotide (NADH) infusions may be used to treat Alzheimer's disease and dementia, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

39. Taurine infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

40. MCPS is a sterile compounding pharmacy located in Santa Ana, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion therapies) to physicians and clinics for administration to patients. At all times relevant herein, Si Pham was the Pharmacist-in-Charge and Ronald McGuff was the sole shareholder and an officer of the corporation that owns MCPS. Board inspections revealed the following violations of Pharmacy Law.

41. Pharmacy technicians, facility foremen, plant managers, corporate representatives, chemists, engineers and/or other non-licensed staff possessed keys and alarm codes for areas where dangerous drugs were compounded and accessed those areas when pharmacists were not present.

42. In 2017 and 2018, MCPS received reports of adverse drug effects (i.e., headaches, high fevers, diarrhea, extreme fatigue, loss of consciousness, chills and nausea) suffered by patients after being administered infusions of lipoic acid compounded and dispensed by MCPS.

43. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the FDA warned compounders not to use a dietary grade bulk substance distributed by a manufacturer to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

44. MCPS compounded and dispensed sterile injectable drugs including hydrogen peroxide 3%, lipoic acid 40mg/ml, DMPS 50mg/ml, NADH 50 mg/ml and methylcobalamin 5mg/ml 30ml using ingredients (i.e., dietary grade, topical grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

45. On November 13, 2019, the Board issued an Order of Correction to MCPS for this unsafe practice and directed Si Pham to send a plan of correction.

46. On November 22, 2019, the FDA issued a Form FDA 483 to MCPS observing among other violations, that MCPS compounded and dispensed sterile injectable drugs with non-pharmaceutical grade ingredients containing high levels of contaminants (MCPS "currently uses …dietary grade bulk substances in sterile injectable drug products") and observed that the use of non-pharmaceutical grade bulk substances in MCPS's products resulted in a recall of Lipoic Acid 40 mg/ml, 30 ml vials due to a "filmy wispy precipitate" found in on-hand vials of released product and the discontinued production of NADH disodium 50 mg/ml due to out of specification endotoxin results.

47. During the "closeout" meeting on November 22, 2019, both the FDA and Board informed Ronald McGuff and Si Pham about the safety risks associated with MCPS's practice of

compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants and higher bioburden levels than pharmaceutical grade ingredients.

48. On December 5, 2019, MCPS wrote the Board that it was MCPS's "continuing desire and intention to comply with all requirements of California pharmacy laws and expectations of the Board of Pharmacy" and it had stopped the dispensing and compounding of sterile preparations compounded with dietary grade and non-compendial grade raw materials "regardless of whether the bulk drug substance appears on the FDA's Category 1 list until further guidance and/or clarification from both the FDA and CA BOP." On December 16, 2019, MCPS wrote the FDA that "[i]n the near term, MCPS has suspended compounding drug preparations containing the components listed in the observation and all USP dietary grade supplements. Drug preparation lots compounded with the listed components will not be dispensed...Corrective Actions for Observation 7: Suspend compounding and dispensing drug preparations utilizing non-pharmaceutical grade components until pharmaceutical grade replacements can be procured or until alternate assurance of material quality and fitness for intended used can be established."

49. However, MCPS continued to compound and dispense a large volume of sterile injectable drugs from inappropriate ingredients, including methylcobalamin and lipoic acid after making those representations to the Board and FDA and receiving the Compounding Safety Alerts.

50. MCPS compounded sterile injectable lipoic acid 40mg/ml 30 ml MDV (Lot No. 18M0991) and DMPS 50mg/ml 5ml SDV (Lot No. 18J1081) containing particulate or precipitate but failed to provide the Board with notice of the recalls of those drugs within twelve hours as required.

51. Patients reported to MCPS that they suffered adverse drug effects (i.e., excruciating pain) from one of its sterile injectable drug products, vitamin D3 10,00IU/ML 30ML MDV (Lot No. 20F1501:0920) but it failed to report those adverse effects to the Board within twelve hours as required.

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52. MCPS compounded sterile injectable chromium (Lot No. 19K411) without a master formula describing the equipment to be used, inactive ingredients to be used and the specific and essential compounding steps used to prepare that infusion.

53. MCPS did not possess all of the policies and procedures required to compound sterile injectable drugs, including procedures for quality assurance programs, cleaning and maintenance of ISO environments and for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. It also did not possess a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

54. From January 17 through February 23, 2018, there was a 12.6% patch in the HEPA filter of MCPS's primary engineering control devices in Room 107 which was not completely repaired. Yet, MCPS continued to compound at least ten sterile injectable drugs with that primary engineering control device before it was re-certified and tested on February 23, 2018.

55. In November 2019, pharmacy technicians performed prefatory compounding functions, (washed and prepared empty vials) without a pharmacist being present on the premises.

56. In August and September 2020, MCPS failed to document the manufacturer of at least one component for the sterile injectable drug, methylcobalamin.

57. Despite the filing of the Accusation, the discussions with the FDA and Board about safety risks associated with using inappropriate ingredients, the receipt of the FDA Form 483, the receipt of the Board's Order of Correction and the Written Notice and Respondents' promises to cease compounding and dispensing sterile injectable drugs with dietary grade and non-compendial substances, from at least June 1, 2021 through December 1, 2021, MCPS continued to compound and dispense sterile injectable drugs, methylcobalamin 5mg/mL, glutathione 200mg/mL, taurine, lipoic acid and DMPS using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living

on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

58. In 2021, MCPS received reports of at least six adverse drug effects, including headaches, fever, chills and nausea from sterile injectable drugs compounded and dispensed, but failed to timely report at least four of those adverse drug effects to the Board. It also failed to report at least four of the adverse drug effects immediately to the MedWatch Program of the FDA.

59. On January 24, 2022, the Board issued an Order of Correction to Respondents for their continued use of ingredients in sterile injectable products that lacked quality and a Written Notice for the failure to report adverse drug effects to the Board within twelve hours and immediately to the MedWatch Program of the FDA.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that they manufactured, held (including under insanitary conditions), sold, offered for sale and/or delivered drugs that were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 40 through 59.

SECOND CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drugs Lacking in Quality)

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), in that they compounded sterile injectable drug products lacking in quality as defined by California Code of Regulations, title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 40 through 59.

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THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

62. Respondents are subject to disciplinary action under Code section 4301, subdivision (f) in that those Respondents committed dishonest acts when they falsely claimed that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FOURTH CAUSE FOR DISCIPLINE

(Made Documents that Falsely Represent Facts)

63. Respondents subject to disciplinary action under Code section 4301, subdivision (g) in that those Respondents made documents that falsely represented the existence of a state of facts when they represented in writing that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Security for Pharmacy Premises)

64. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that pharmacy technicians and unlicensed personnel had access to pharmacy premises where dangerous drugs were compounded without a pharmacist being present and had keys to all of the pharmacy premises, as set forth above in paragraphs 40 through 59.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Supervision of Pharmacy Technicians)

65. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4115, subdivision (a) as defined by Business and Professions Code section 4023.5, in that pharmacy technicians washed and prepared empty drug vials without a pharmacist on the premises, as set forth above in paragraphs 40 through 59.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall of Sterile Drug Products)

66. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code sections 4127.1, subdivision (e)(3) and 4127.8, subdivision (a) , in that they failed to provide to the Board, within 12 hours, recall notices issued by MCPS for sterile drug products it had compounded, as set forth above in paragraphs 40 through 59.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Drug Effects of Sterile Drug Product)

67. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report to the Board within 12 hours and immediately to the MedWatch program of the FDA, adverse drug effects reported to MCPS, about its sterile injectable drug products, as set forth above in paragraphs 40 through 59.

NINTH CAUSE FOR DISCIPLINE

(Failed to Possess All Policies and Procedures and a Written Quality Assurance Plan for Compounding Sterile Drug Preparations)

68. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, sections 1735.5, 1735.8, subdivision (a) and 1751.3, subdivision (a) because they failed to have all required written policies and procedures for compounding sterile drug preparations and a written quality assurance plan, as set forth in paragraphs 40 through 59 above.

TENTH CAUSE FOR DISCIPLINE

(Compounded with Incomplete Master Formulas)

69. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they compounded sterile injectable drug preparations without a complete written master formula, as set forth in paragraphs 40 through 59 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Logs)

70. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they compounded sterile injectable drug preparations without preparing complete compounding logs, as set forth in paragraphs 40 through 59 above.

TWELFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Drug Products in Uncertified Primary Engineering Control)

71. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (f), in that they compounded sterile injectable drug preparations using an inappropriate primary engineering control device, as set forth in paragraphs 40 through 59 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training or Experience as a Pharmacist Against Respondent Si Pham)

72. Respondent Si Pham is subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a) for his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 40 through 59.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 40 through 59 above.

DISCIPLINE CONSIDERATIONS

74. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 30, 2019, the Board issued Citation Number CI 2017 80272 to MCPS under Business and Professions Code section 4301, subdivision (n) because it

was disciplined by the Alabama Board of Pharmacy for selling, offering to sell, compounding and/or dispensed drugs into Alabama without a permit. That Citation is now final.

OTHER MATTERS

75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Ronald M. McGuff has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Si Van Pham has been a manager and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 49833 issued to Si Van Pham, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 43950, issued to McGuff Compounding Pharmacy Services Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99004, issued to McGuff Compounding Pharmacy Services Inc.;

3. Revoking or suspending Pharmacist License Number RPH 49833, issued to Si Van Pham;

4. Prohibiting McGuff Compounding Pharmacy Services Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Ronald M. McGuff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

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7. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 49833 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering McGuff Compounding Pharmacy Services Inc. and Si Van Pham to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 4/21/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.04.21 07:56:10 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Members of the Board of Pharmacy:

We, the undersigned, write to you from the perspective of Board licensees who agreed to the imposition of discipline on our pharmacy and pharmacist licenses in the case titled *In the Matter of the Accusation Against McGuff Compounding Pharmacy Services, Inc., et al.*, Board Case No. 7176. We reached a settlement of the Accusation, of which this letter is part.

We wish to forthrightly and unequivocally state, here, that as persons with significant experience in pharmacy compounding, we agree with and support the following statements:

- All compounding pharmacies located in California or which provide services to California patients are governed both by relevant sections of federal statutes and regulations applicable to pharmacy compounding, including but not limited to section 501 [21 U.S.C. § 351] of the Federal Food, Drug, and Cosmetic Act (FDCA), which defines "adulterated" drugs to include those prepared, packed, or held under insanitary conditions, and FDCA section 503A [21 U.S.C. § 353a], which sets forth several federal requirements to engage in traditional pharmacy compounding, and by the California Pharmacy Law and its associated regulations;

- Further, best practices demand that section 503A traditional compounding pharmacies not use bulk drug substances that are not graded, nor those not designated by their manufacturers for pharmaceutical use, nor those lacking an appropriate USP/NF monograph;

- Best practices further demand that section 503A traditional compounding pharmacies only use bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph; (2) if such monograph does not exist, are drug substances that are components of FDA-approved drugs; and (3) if such monograph does not exist and the drug substance is not a component of an FDA-approved drug, then it must be on a list developed by the Secretary through regulations issued by the Secretary under subsection (c); and

- Best practices also demand that section 503A traditional compounding pharmacies: (1) only use bulk drug substances that are manufactured by an FDA-registered establishment; and (2) that are accompanied by valid certificates of analysis for each bulk drug substance.

We look forward to working with the FDA and the Board to be sure that Californians have access to prescribed medications that are held to the highest degree of quality assurance.

McGuff Compounding Pharmacy Services, Inc.

Ronald McGuff, CEO Date

Si Pham, Pharmacist-In-Charge Date

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563,** **Respondent.**	**Case Nos. 23-070-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563,** **Respondent.**	**Case No. 23-070-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR McGUFF COMPOUNDING PHARMACY SERVICES, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Compounding Pharmacy Services, Inc.
2921 W MacArthur Blvd., Ste. 142
Santa Ana, CA 92704

McGUFF COMPANY, INC.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5D

FILED
FEB 2 8 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPOUNDING PHARMACY SERVICES, INC,** **Pharmacy License No. PH01563, and** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondents.**	**CASE NOS. 23-070-PH-O** **23-070-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent McGuff Compounding Pharmacy Services, Inc, Pharmacy License No. PH01563 (McGuff Pharmacy), located in Santa Ana, California, was a pharmacy licensed by the Board, and McGuff Company, Inc, Wholesale License No. WH01300 (McGuff Company), located in Santa Ana, California, was a medical products wholesale distributor licensed by the Board.

FACTUAL ALLEGATIONS

2. McGuff Pharmacy and McGuff Company are both owned by Ronald M. McGuff.

3. On or about March 1, 2023, the California State Board of Pharmacy entered an Order in Case Nol. 7176 approving a stipulated settlement for voluntary surrender of Respondent McGuff Pharmacy's Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004, for numerous violations of federal and California state law related to compounding drug products, including, without limitation, various provisions of 21 U.S.C. § 353a, 42 U.S.C. §

262, Cal. Business and Professions Code § 4000 *et seq.*, and Cal. Code of Regulations, Title 16, Section 1700 *et seq.* (SEE EXHBIT A HERETO).

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications. *See also* 42 U.S.C. § 262 (regulation of biological products).

5. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

8. Respondents, their owner, and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and violated various provisions of 21 U.S.C. § 353a,

42 U.S.C. § 262, Cal. Business and Professions Code § 4000 *et seq*., and Cal. Code of Regulations, Title 16, Section 1700 *et seq*. as detailed in the California State Board of Pharmacy's Order entered in Case Nol. 7176. Respondents are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the licenses of these Respondents.

Signed this 26th day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

January 30, 2023

CERTIFIED MAIL

McGuff Compounding Pharmacy Services Inc.
Attn: Ronald McGuff, President
2921 W. MacArthur Blvd, Suite 142
Santa Ana, CA 92704

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

Dear Mr. McGuff:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order regarding the above-referenced matter. Your attention is directed to pages 4 - 8 of the document.

Effective at 5:00 p.m. on March 1, 2023, Pharmacy Permit No. PHY 43950 and Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., is hereby surrendered and accepted by the Board and subject to the terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, Administrative Case Analyst, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

Enclosure(s)
cc: Desiree I. Kellogg, DAG
Joshua A. Room, SDAG
Tony J. Park, Pharm.D., J.D.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7176
McGuff Compounding Pharmacy Services Inc., PHY 43950 & LSC 99004

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McGuff Compounding Pharmacy Services Inc. Attn: Ronald McGuff, President 2921 W. MacArthur Blvd, Suite 142 Santa Ana, CA 92704	7013 2630 0001 5115 0571
Tony J. Park, Pharm.D., J.D. California Pharmacy Lawyers 9090 Irvine Center Drive Irvine, CA 92618-6713	7013 2630 0001 5115 0595

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on January 30, 2023, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 30, 2023, at Sacramento, California.

Susan Cappello, Enforcement Manager

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER

Pharmacy Permit No. PHY 43950
Sterile Compounding License No. LSC 99004,

and

SI VAN PHAM

Pharmacist License No. RPH 49833

Respondents.

Agency Case No. 7176

OAH No. 2021120276

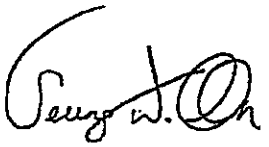
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2023.

It is so ORDERED on January 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
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San Diego, CA 92101
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San Diego, CA 92186-5266
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JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue; Suite 11000
San Francisco, CA 94102
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 OAH No. 2021120276 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation with respect to Respondents McGuff Compounding Pharmacy Services Inc. and Si Van Pham.

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General, and Joshua A. Room, Supervising Deputy Attorney General.

2. Respondents are represented in this proceeding by attorney Tony J. Park, Pharm.D., J.D., whose address is: California Pharmacy Lawyers, Law Offices of Tony J. Park, Inc., 9090 Irvine Center Drive, Irvine, CA 92618, telephone (949) 336-7854.

3. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc. Ronald M. McGuff has served or been listed in Board records as the sole shareholder and President, Vice-President, and Secretary of McGuff Compounding Pharmacy Services Inc. (Respondent McGuff Compounding aka MCPS). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to Respondent McGuff Compounding aka MCPS. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

5. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Respondent Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed. Respondent Pham has served and been listed in Board records as Pharmacist-in-Charge of Respondent McGuff Compounding aka MCPS since July 9, 2016.

JURISDICTION

6. Accusation No. 7176 was filed before the Board, against Respondents. Accusation No. 7176 and all other statutorily required documents were properly served on Respondents on October 28, 2021. Respondents timely filed their Notice(s) of Defense contesting the Accusation. First Amended Accusation No. 7176 was filed before the Board, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on April 21, 2022. A copy of First Amended Accusation No. 7176 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 7176. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order on their respective permits and licenses.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel attendance of witnesses and production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 7176, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit, Sterile Compounding License, and Pharmacist License. For the purposes of resolving this matter without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for charges in the First Amended Accusation, and Respondents hereby give up their right to contest those charges.

11. Respondents agree that their Pharmacy Permit, Sterile Compounding License, and Pharmacist License are each and severally subject to discipline and they agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

DESIRED LICENSE CATEGORY TRANSITION

12. Respondent MCPS has decided to seek a transition from being a licensed pharmacy engaged in compounding (a Section 503A facility under federal law) to being a registered and licensed outsourcing facility (a Section 503B facility under federal law). This will entail an application to the Food and Drug Administration (FDA) for registration under Section 503B as an outsourcing facility, and then an application to the Board to be licensed in California as an outsourcing facility. It could take some significant time for MCPS to prepare for and make these applications. In the interim, the MCPS facility will cease functioning as a pharmacy on the effective date of the Decision and Order by the Board of Pharmacy adopting this stipulation.

13. This settlement of the First Amended Accusation does not depend on whether MCPS, any successor or assign thereof, or any entity sharing ownership or management with MCPS, actually submits a subsequent application to the Board for licensure as an outsourcing facility. In the event such application is submitted, the Board will give it the same consideration it would any other application to be licensed as an outsourcing facility. This settlement does not preclude the Board from granting that license. Nor is the Board under any obligation from this settlement to grant that license. Any such application will receive ordinary and fair consideration for licensure. If such an outsourcing facility license is granted, there is one term below that will be applied by the Board to that license, and which Respondent MCPS acknowledges will apply to itself, any successor or assign, or any entity sharing ownership or management with Respondent MCPS.

IMMEDIATE CEASE AND DESIST

14. As of the last date of all signatures on this Stipulated Settlement and Disciplinary Order, both Respondents agree to voluntarily and completely cease and desist compounding, or sales or transfers of compounded preparations, using any active ingredients or drug products named or identified in First Amended Accusation No. 7176, or any other active ingredient or drug product that is not graded for pharmaceutical use.

15. Any compounding by Respondents, or sales or transfers of compounded preparations, using such active ingredients or drug products after that date shall constitute unprofessional conduct and further cause for discipline by both Respondents, and may be considered by the Board in deciding whether to grant or deny any subsequent application by Respondent MCPS, its successor or assign, or any entity sharing ownership or management with Respondent MCPS, including but not limited to a subsequent application for an outsourcing facility license.

CONTINGENCY

16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

17. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

18. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

19. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

AS TO RESPONDENT MCGUFF COMPOUNDING AKA MCPS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43950, and Sterile Compounding License No. LSC 99004, both issued to Respondent McGuff Compounding aka MCPS, are each and severally surrendered and accepted by the Board.

20. **Definition: Respondent**

For the purposes of paragraphs 20-33, "Respondent" shall refer to Respondent McGuff Compounding aka MCPS. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

21. The surrender of Respondent's Pharmacy Permit and Sterile Compounding License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

22. Respondent shall lose all rights and privileges as a pharmacy and to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

23. Respondent shall be jointly and severally liable to the Board, along with Respondent Pham, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order.

24. Within (5) business days of the date this Stipulated Settlement and Disciplinary Order is fully executed, Respondent shall submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board. Any transfers of drug inventory shall be conducted in compliance with state and federal law.

25. If permitted by state and federal law, Respondent may transfer current inventory to its commonly-owned facilities as necessary to prepare for testing and other requirements to establish subsequent eligibility for an outsourcing facility registration and/or license.

26. Respondent shall cause to be delivered to the Board its pocket license and, if any were issued, its wall certificates, on or before the effective date of the Decision and Order.

27. Respondent shall also, by the effective date of the Decision and Order, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of its written notice to the Board. For purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

28. Respondent shall also, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

29. Neither Respondent nor its successor or assign, nor any entity sharing ownership or management with Respondent, shall apply to the Board for any permit, license, or registration issued by the Board for a period of three (3) years, except that at any time it is eligible for same:

- Respondent may submit an application for an outsourcing facility license;
- Respondent may apply for a change of location for its wholesaler license (WLS 2947), so long as there is no change in ownership or management structure, or any other substantive change aside from the change in location; and
- Should the Board change the name or category of licensure applicable to the WLS license, Respondent may apply to adopt this change, so long as there is no change in ownership or management structure, or other substantive change.

30. If Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, ever applies for licensure, including as an outsourcing facility, or petitions for reinstatement, the Board shall treat it as a new application for licensure. The applicant/petitioner must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and charges and allegations in First Amended Accusation No. 7176 shall be deemed to be supported by a factual basis and not contested by Respondent when the Board determines whether to grant or deny the application or petition.

31. If an application for an outsourcing facility license is submitted by Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, the Board may in addition consider, in deciding whether to grant or deny that license: whether Respondent met its agreement for the pharmacy to cease and desist compounding, sales, or transfers of drug preparations using active ingredients or drug products named or identified in First Amended Accusation No. 7176, or that are not graded for pharmaceutical use; and whether the Board has received full payment of the costs of investigation and enforcement in this case.

32. If an outsourcing facility license is granted by the Board to Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, that applicant/licensee shall retain, at its own expense, for a period of one (1) year after licensure, an independent consultant for the outsourcing facility approved in advance by the Board or its designee.

33. That independent consultant shall be a pharmacist licensed in good standing by the Board, and shall be responsible for conducting in-person inspections to review the operations of the outsourcing facility on a monthly basis for compliance with applicable state and federal laws. The independent consultant shall prepare and submit written reports directly to Board staff; such reports shall not go first to or be made available to the licensee by the independent consultant.

AS TO RESPONDENT PHAM

IT IS HEREBY ORDERED that Pharmacist License No. RPH 49833, issued to Respondent Pham, is revoked. However, the revocation is stayed and Respondent Pham is placed on probation for thirty-five (35) months on the following terms and conditions:

34. **Definition: Respondent**

For the purposes of paragraphs 34-52, "Respondent" shall refer to Respondent Pham.

35. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

36. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

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37. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

38. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

39. **Cooperate with Board Staff**

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

40. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current pharmacist license with the Board, including any period during which probation is tolled. Failure to maintain an active, current pharmacist license shall be considered a violation of probation.

If Respondent's pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

41. **Submission of Letter to Board**

Respondent shall, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make

whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

42. **Reimbursement of Board Costs**

Respondent shall be jointly and severally liable to the Board, along with Respondent MCPS, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order. It shall be a condition precedent to successful completion of probation that these costs were timely paid. Failure to pay costs by the deadline shall also be considered a violation of probation.

43. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

44. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in

California for the minimum of one hundred (100) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

45. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll, at Respondent's expense, in a course in ethics approved in advance by the Board or its designee, that complies with California Code of Regulations, title 16, section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

46. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90) days of the effective date of this decision and provide written proof thereof to the Board.

Failure to timely divest any legal or beneficial interest(s) or to immediately provide documentation thereof to the Board shall be considered a violation of probation.

47. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in name, residence or mailing address, email address, or phone number, shall be considered a violation of probation.

48. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7176 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each employer(s), and the name(s) and telephone number(s) of all direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s), and Respondent's work schedule, if known. Respondent shall also include reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee concerning Respondent's work status, performance, and monitoring.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause his (a) direct supervisor, (b) pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7176, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Roard in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby.

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If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 7176, and the terms and conditions imposed thereby, in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s), or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board, shall be considered a violation of probation. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor, or volunteer.

49. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if Respondent or that entity retains, at his/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a monthly basis for compliance by Respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Respondent with the obligations of his supervisory position, for the duration of Respondent's probation period.

Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

50. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his pharmacist license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender will constitute a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

51. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____
Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/14/22

Ronald M. McGuff

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY SERVICES INC.
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-14-22

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/14/2022

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 14, 2022

Respectfully submitted,

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/s/ Desiree I. Kellogg

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc., Ronald M. McGuff, sole shareholder and President, Vice-President and Secretary and Si Pham, Pharmacist-in-Charge since July 9, 2016 (McGuff Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

3. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to McGuff Compounding Pharmacy Services Inc. (MCPS). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Si Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed.

JURISDICTION

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq.*) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq.*).

7. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license

by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. Code section 4113, subdivision (c) states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. Code section 4115, subdivision (a) states:

A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

13. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or re-packaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

///

14. Code section 4127.1, subdivisions (e)(3) and (f) state:

(e)(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

15. Code section 4127.8, subdivision (a) states:

A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

16. Section 4169 subdivision (a)(2) of the Code state:

(a) A person or entity shall not do any of the following:

...

(2) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

17. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

...

18. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

...

19. Code section 4307, subdivision (a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) states:

A drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

25. California Code of Regulations, title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

26. California Code of Regulations, title 16, section 1735.2, subdivisions (e), (g) and (h) state:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

...

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength.

27. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F) states:

For each compounded drug preparation, pharmacy records shall include: A compounding log consisting of a single document containing all of the following: the manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

28. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency,

quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

29. California Code of Regulations, title 16, section 1735.8, subdivision (a) states:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

30. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable).

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

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31. California Code of Regulations, title 16, section 1751.4, subdivision (f) states:

Pharmacies preparing-g sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

COST RECOVERY

32. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DEFINITIONS

33. Hydrogen peroxide infusions may be used to treat inflammation, are not Food and Drug Administration (FDA) approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

34. Dimercapto-propane sulfonic acid (DMPS) infusions may be used to treat mercury and other metal poisoning, are not FDA approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

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35. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

36. Lipoic acid infusions may be used to treat nerve pain, are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

37. Methylcobalamin infusions may be used to treat neurological conditions and pain, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

38. Disodium nicotinamide adenine dinucleotide (NADH) infusions may be used to treat Alzheimer's disease and dementia, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

39. Taurine infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

40. MCPS is a sterile compounding pharmacy located in Santa Ana, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion therapies) to physicians and clinics for administration to patients. At all times relevant herein, Si Pham was the Pharmacist-in-Charge and Ronald McGuff was the sole shareholder and an officer of the corporation that owns MCPS. Board inspections revealed the following violations of Pharmacy Law.

41. Pharmacy technicians, facility foremen, plant managers, corporate representatives, chemists, engineers and/or other non-licensed staff possessed keys and alarm codes for areas where dangerous drugs were compounded and accessed those areas when pharmacists were not present.

42. In 2017 and 2018, MCPS received reports of adverse drug effects (i.e., headaches, high fevers, diarrhea, extreme fatigue, loss of consciousness, chills and nausea) suffered by patients after being administered infusions of lipoic acid compounded and dispensed by MCPS.

43. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the FDA warned compounders not to use a dietary grade bulk substance distributed by a manufacturer to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

44. MCPS compounded and dispensed sterile injectable drugs including hydrogen peroxide 3%, lipoic acid 40mg/ml, DMPS 50mg/ml, NADH 50 mg/ml and methylcobalamin 5mg/ml 30ml using ingredients (i.e., dietary grade, topical grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

45. On November 13, 2019, the Board issued an Order of Correction to MCPS for this unsafe practice and directed Si Pham to send a plan of correction.

46. On November 22, 2019, the FDA issued a Form FDA 483 to MCPS observing among other violations, that MCPS compounded and dispensed sterile injectable drugs with non-pharmaceutical grade ingredients containing high levels of contaminants (MCPS "currently uses …dietary grade bulk substances in sterile injectable drug products") and observed that the use of non-pharmaceutical grade bulk substances in MCPS's products resulted in a recall of Lipoic Acid 40 mg/ml, 30 ml vials due to a "filmy wispy precipitate" found in on-hand vials of released product and the discontinued production of NADH disodium 50 mg/ml due to out of specification endotoxin results.

47. During the "closeout" meeting on November 22, 2019, both the FDA and Board informed Ronald McGuff and Si Pham about the safety risks associated with MCPS's practice of

compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants and higher bioburden levels than pharmaceutical grade ingredients.

48. On December 5, 2019, MCPS wrote the Board that it was MCPS's "continuing desire and intention to comply with all requirements of California pharmacy laws and expectations of the Board of Pharmacy" and it had stopped the dispensing and compounding of sterile preparations compounded with dietary grade and non-compendial grade raw materials "regardless of whether the bulk drug substance appears on the FDA's Category 1 list until further guidance and/or clarification from both the FDA and CA BOP." On December 16, 2019, MCPS wrote the FDA that "[i]n the near term, MCPS has suspended compounding drug preparations containing the components listed in the observation and all USP dietary grade supplements. Drug preparation lots compounded with the listed components will not be dispensed...Corrective Actions for Observation 7: Suspend compounding and dispensing drug preparations utilizing non-pharmaceutical grade components until pharmaceutical grade replacements can be procured or until alternate assurance of material quality and fitness for intended used can be established."

49. However, MCPS continued to compound and dispense a large volume of sterile injectable drugs from inappropriate ingredients, including methylcobalamin and lipoic acid after making those representations to the Board and FDA and receiving the Compounding Safety Alerts.

50. MCPS compounded sterile injectable lipoic acid 40mg/ml 30 ml MDV (Lot No. 18M0991) and DMPS 50mg/ml 5ml SDV (Lot No. 18J1081) containing particulate or precipitate but failed to provide the Board with notice of the recalls of those drugs within twelve hours as required.

51. Patients reported to MCPS that they suffered adverse drug effects (i.e., excruciating pain) from one of its sterile injectable drug products, vitamin D3 10,00IU/ML 30ML MDV (Lot No. 20F1501:0920) but it failed to report those adverse effects to the Board within twelve hours as required.

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52. MCPS compounded sterile injectable chromium (Lot No. 19K411) without a master formula describing the equipment to be used, inactive ingredients to be used and the specific and essential compounding steps used to prepare that infusion.

53. MCPS did not possess all of the policies and procedures required to compound sterile injectable drugs, including procedures for quality assurance programs, cleaning and maintenance of ISO environments and for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. It also did not possess a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

54. From January 17 through February 23, 2018, there was a 12.6% patch in the HEPA filter of MCPS's primary engineering control devices in Room 107 which was not completely repaired. Yet, MCPS continued to compound at least ten sterile injectable drugs with that primary engineering control device before it was re-certified and tested on February 23, 2018.

55. In November 2019, pharmacy technicians performed prefatory compounding functions, (washed and prepared empty vials) without a pharmacist being present on the premises.

56. In August and September 2020, MCPS failed to document the manufacturer of at least one component for the sterile injectable drug, methylcobalamin.

57. Despite the filing of the Accusation, the discussions with the FDA and Board about safety risks associated with using inappropriate ingredients, the receipt of the FDA Form 483, the receipt of the Board's Order of Correction and the Written Notice and Respondents' promises to cease compounding and dispensing sterile injectable drugs with dietary grade and non-compendial substances, from at least June 1, 2021 through December 1, 2021, MCPS continued to compound and dispense sterile injectable drugs, methylcobalamin 5mg/mL, glutathione 200mg/mL, taurine, lipoic acid and DMPS using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living

on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

58. In 2021, MCPS received reports of at least six adverse drug effects, including headaches, fever, chills and nausea from sterile injectable drugs compounded and dispensed, but failed to timely report at least four of those adverse drug effects to the Board. It also failed to report at least four of the adverse drug effects immediately to the MedWatch Program of the FDA.

59. On January 24, 2022, the Board issued an Order of Correction to Respondents for their continued use of ingredients in sterile injectable products that lacked quality and a Written Notice for the failure to report adverse drug effects to the Board within twelve hours and immediately to the MedWatch Program of the FDA.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that they manufactured, held (including under insanitary conditions), sold, offered for sale and/or delivered drugs that were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 40 through 59.

SECOND CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drugs Lacking in Quality)

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), in that they compounded sterile injectable drug products lacking in quality as defined by California Code of Regulations, title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 40 through 59.

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THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

62. Respondents are subject to disciplinary action under Code section 4301, subdivision (f) in that those Respondents committed dishonest acts when they falsely claimed that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FOURTH CAUSE FOR DISCIPLINE

(Made Documents that Falsely Represent Facts)

63. Respondents subject to disciplinary action under Code section 4301, subdivision (g) in that those Respondents made documents that falsely represented the existence of a state of facts when they represented in writing that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Security for Pharmacy Premises)

64. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that pharmacy technicians and unlicensed personnel had access to pharmacy premises where dangerous drugs were compounded without a pharmacist being present and had keys to all of the pharmacy premises, as set forth above in paragraphs 40 through 59.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Supervision of Pharmacy Technicians)

65. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4115, subdivision (a) as defined by Business and Professions Code section 4023.5, in that pharmacy technicians washed and prepared empty drug vials without a pharmacist on the premises, as set forth above in paragraphs 40 through 59.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall of Sterile Drug Products)

66. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code sections 4127.1, subdivision (e)(3) and 4127.8, subdivision (a) , in that they failed to provide to the Board, within 12 hours, recall notices issued by MCPS for sterile drug products it had compounded, as set forth above in paragraphs 40 through 59.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Drug Effects of Sterile Drug Product)

67. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report to the Board within 12 hours and immediately to the MedWatch program of the FDA, adverse drug effects reported to MCPS, about its sterile injectable drug products, as set forth above in paragraphs 40 through 59.

NINTH CAUSE FOR DISCIPLINE

(Failed to Possess All Policies and Procedures and a Written Quality Assurance Plan for Compounding Sterile Drug Preparations)

68. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, sections 1735.5, 1735.8, subdivision (a) and 1751.3, subdivision (a) because they failed to have all required written policies and procedures for compounding sterile drug preparations and a written quality assurance plan, as set forth in paragraphs 40 through 59 above.

TENTH CAUSE FOR DISCIPLINE

(Compounded with Incomplete Master Formulas)

69. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they compounded sterile injectable drug preparations without a complete written master formula, as set forth in paragraphs 40 through 59 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Logs)

70. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they compounded sterile injectable drug preparations without preparing complete compounding logs, as set forth in paragraphs 40 through 59 above.

TWELFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Drug Products in Uncertified Primary Engineering Control)

71. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (f), in that they compounded sterile injectable drug preparations using an inappropriate primary engineering control device, as set forth in paragraphs 40 through 59 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training or Experience as a Pharmacist Against Respondent Si Pham)

72. Respondent Si Pham is subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a) for his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 40 through 59.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 40 through 59 above.

DISCIPLINE CONSIDERATIONS

74. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 30, 2019, the Board issued Citation Number CI 2017 80272 to MCPS under Business and Professions Code section 4301, subdivision (n) because it

was disciplined by the Alabama Board of Pharmacy for selling, offering to sell, compounding and/or dispensed drugs into Alabama without a permit. That Citation is now final.

OTHER MATTERS

75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Ronald M. McGuff has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Si Van Pham has been a manager and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 49833 issued to Si Van Pham, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 43950, issued to McGuff Compounding Pharmacy Services Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99004, issued to McGuff Compounding Pharmacy Services Inc.;

3. Revoking or suspending Pharmacist License Number RPH 49833, issued to Si Van Pham;

4. Prohibiting McGuff Compounding Pharmacy Services Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Ronald M. McGuff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

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7. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 49833 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering McGuff Compounding Pharmacy Services Inc. and Si Van Pham to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 4/21/2022

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2022.04.21 07:56:10 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Members of the Board of Pharmacy:

We, the undersigned, write to you from the perspective of Board licensees who agreed to the imposition of discipline on our pharmacy and pharmacist licenses in the case titled *In the Matter of the Accusation Against McGuff Compounding Pharmacy Services, Inc., et al.*, Board Case No. 7176. We reached a settlement of the Accusation, of which this letter is part.

We wish to forthrightly and unequivocally state, here, that as persons with significant experience in pharmacy compounding, we agree with and support the following statements:

- All compounding pharmacies located in California or which provide services to California patients are governed both by relevant sections of federal statutes and regulations applicable to pharmacy compounding, including but not limited to section 501 [21 U.S.C. § 351] of the Federal Food, Drug, and Cosmetic Act (FDCA), which defines "adulterated" drugs to include those prepared, packed, or held under insanitary conditions, and FDCA section 503A [21 U.S.C. § 353a], which sets forth several federal requirements to engage in traditional pharmacy compounding, and by the California Pharmacy Law and its associated regulations;

- Further, best practices demand that section 503A traditional compounding pharmacies not use bulk drug substances that are not graded, nor those not designated by their manufacturers for pharmaceutical use, nor those lacking an appropriate USP/NF monograph;

- Best practices further demand that section 503A traditional compounding pharmacies only use bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph; (2) if such monograph does not exist, are drug substances that are components of FDA-approved drugs; and (3) if such monograph does not exist and the drug substance is not a component of an FDA-approved drug, then it must be on a list developed by the Secretary through regulations issued by the Secretary under subsection (c); and

- Best practices also demand that section 503A traditional compounding pharmacies: (1) only use bulk drug substances that are manufactured by an FDA-registered establishment; and (2) that are accompanied by valid certificates of analysis for each bulk drug substance.

We look forward to working with the FDA and the Board to be sure that Californians have access to prescribed medications that are held to the highest degree of quality assurance.

McGuff Compounding Pharmacy Services, Inc.

Ronald McGuff, CEO Date

Si Pham, Pharmacist-In-Charge Date

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPANY, INC,** **Wholesale License No. WH01300,** **Respondent.**	**Case Nos. 23-070-WH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 20th day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **McGUFF COMPANY, INC.,** **Wholesale License No. WH01300,** **Respondent.**	**Case No. 23-070-WH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR McGUFF COMPANY, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Company, Inc.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

McGuff Compounding Pharmacy Services, Inc.
2921 W MacArthur Blvd., Ste. 142
Santa Ana, CA 92704

McGUFF COMPANY, INC.
3524 W. Lake Center Drive #B
Santa Ana, CA 92704

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**CASE NO. 23-411-PH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Revive Rx, Pharmacy License No. PH04215, located in Houston, Texas, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. From October 10, 2023, through January 10, 2024, Respondent compounded and dispensed drug products to Nevada patients using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, Respondent dispensed compounded injectable peptides, including, without limitation, AOD9604, Ipamorelin, Kisspeptin, and MOTs-C Acetate. Respondent also dispensed KPV 500mcg/BPX-157 20mcg and Dihexa in capsule form and Selank 7.5mg in a nasal spray.

3. Respondent compounded and dispensed high-risk sterile products to Nevada patients with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.

APPLICABLE LAW

4. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications.

5. Any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

8. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

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COUNT ONE

Violation of Federal and State Compounding Law/Unprofessional Conduct

9. Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of 21 U.S.C. § 353a, NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a as alleged in paragraphs 2-3 herein. Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

Signed this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**Case No. 23-411-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**Case No. 23-411-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR REVIVE RX

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Revive Rx
3831 Golf Dr #A
Houston, TX 77018

Philip E. M. Crooker, Esq.
PO Box 339
Tigerville, SC 29688

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY, Pharmacy License No. PH02281,** **Respondent.**	**CASE NO. 23-428-PH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Injured Workers Pharmacy, LLC, Pharmacy License No. PH02281, located in Andover, Massachusetts, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. In June of 2023 Respondent entered into a settlement agreement with the U.S. Department of Justice, the Drug Enforcement Administration, and the Department of Labor, resolving Respondent's violations of federal law related to dispensing of controlled substances (Settlement Agreement - SEE EXHBIT A HERETO).

3. In 2022, Respondent dispensed 1,573 controlled substance prescriptions to Nevada patients in 2022 and dispensed 2, 196 controlled substance prescriptions to Nevada patients in 2023.

APPLICABLE LAW

4. A pharmacy engaged in the practice of dispensing controlled substances in Nevada shall comply in pertinent part with the provisions of the Controlled Substances Act

(CSA), Title 21 United States Code (21 U.S.C.) 801-971, and DEA regulations, Title 21, Code of Federal Regulations (21 CFR) Parts 1300 to 1316.

5. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

7. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act/Unprofessional Conduct

8. Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971, and DEA regulations, Title 21, Code of Federal Regulations (21 CFR) Parts 1300 to 1316, as detailed in the Settlement Agreement. Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and therefore subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of this Respondent.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

Exhibit A

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into by and between the United States of America, acting through the United States Department of Justice, the Drug Enforcement Administration ("DEA"), and the Department of Labor (collectively, the "United States"); and Injured Workers Pharmacy LLC ("IWP"). The United States and IWP are each referred to herein as a "Party" and collectively as the "Parties."

RECITALS

A. IWP is a mail-order pharmacy that is located at 300 Federal St, Andover, Massachusetts. IWP dispenses and ships prescription drugs, including controlled substances, across the United States, primarily to workers who have been injured on the job. IWP is a pharmacy registered with the DEA.

B. The DEA is the Department of Justice component agency primarily responsible for enforcing the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, et seq., and is vested with the responsibility of investigating violations of the CSA.

C. The United States Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the CSA. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

D. The Department of Labor's Office of Worker Compensation Programs administers workers compensation claims under the Federal Workers Compensation Act. Each pharmacy submitting claims for payment to the Department of Labor pursuant to that Act "signifies that the service for which reimbursement is sought was performed as described, necessary, appropriate and properly billed in accordance with accepted industry standards." 20 C.F.R. § 10.801(d). In 2018, the Department of Labor began requiring pharmacies to pre-

adjudicate federal workers compensation prescription claims electronically through a pharmacy benefit manager. The Department of Labor required pre-adjudication to curtail opioid abuse among injured federal workers.

E. Each DEA registrant is required to conduct its operations in accordance with the CSA and the regulations promulgated thereunder. Under the CSA, a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The prescriber has a responsibility for proper prescribing, "but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

F. Beginning in or around June 2018, the United States and the Attorney General for the Commonwealth of Massachusetts (the "Massachusetts AG") began investigating, among other things, IWP's processes and documentation relating to the dispensing of controlled substances. The two investigations proceeded in parallel until June 2020, when IWP resolved the Massachusetts AG's investigation by settling with the Massachusetts AG for $11 million and agreeing to permanent injunctive relief in a stipulated consent judgment (the "Massachusetts AG Consent Judgment"). The settlement with the Massachusetts AG concerned IWP's dispensing practices from 2008 to 2019. The United States' investigation concerned IWP's dispensing practices, as discussed further below, from 2014 through 2019.

G. Prior to and in connection with the Massachusetts AG Consent Judgment, IWP implemented changes to its policies and procedures concerning dispensing controlled substances, including opioids.

H. IWP admits, acknowledges, and accepts its responsibility for the following facts:

a. Between January 1, 2014, and July 31, 2019, IWP received numerous

prescriptions with "red flags," including high doses of opioids, early refills, and "Holy Trinities." A Holy Trinity occurs when an opioid, a benzodiazepine, and a muscle relaxant are prescribed simultaneously to a patient. "Red flags" may indicate a prescriber issued a prescription for a reason other than a legitimate medical purpose, such as abuse or diversion. Pharmacists must review and resolve such "red flags" before filling any prescription. When IWP received prescriptions with "red flags" between January 1, 2014, and July 31, 2019, IWP pharmacists did not always resolve the "red flags" before filling those prescriptions. Even though IWP implemented process improvements beginning in 2017, IWP pharmacists did not have a consistent process or documentation with respect to resolving "red flags."

b. IWP dispensed medications to injured federal workers and submitted claims for payment to the Department of Labor. Between December 12, 2017, and September 26, 2019, the Department of Labor's pharmacy benefit manager issued drug utilization review ("DUR") alerts for 1,456 claims for federal workers' prescriptions for issues such as drug interactions, potential allergic reactions, and therapeutic duplication of opioids. A DUR helps pharmacists ensure that prescribed drugs are appropriate and medically necessary. To clear those DUR rejections and ultimately receive payment from the Department of Labor, IWP's non-pharmacy, claims employees routinely submitted override codes representing that IWP had consulted with prescribers about the DUR alerts. The IWP claims employees, who lacked clinical pharmacy experience and training, submitted the overrides without consulting with IWP pharmacists. Because IWP pharmacists were not aware of the rejections, they did not consult with prescribers in response to the DUR alerts received from the Department of Labor, as represented by IWP claims employees. The foregoing conduct set out in subparagraphs (a) through (b) of Paragraph H is referred to below as the "Covered Conduct."

I. In May 2020, IWP self-disclosed to the Department of Labor that the DUR alerts issue affected 821 claims and offered to repay 256 of them.

J. The United States contends that it has certain civil and administrative claims for civil monetary penalties, injunctive relief, and administrative remedies against IWP under the CSA and its implementing regulations based upon the Covered Conduct. Such civil and administrative claims under the CSA include violations of 21 U.S.C. §§ 827(a)(3), 842(a)(1), 843(a)(2), and the following implementing regulations: 21 C.F.R. §§ 1301.19(b), 1301.71(a), 1304.21(a), 1306.04(a), 1306.05(a), 1306.06, and 1307.02.

K. The United States also contends that it has certain federal civil claims against IWP for submitting or causing the submission of false claims for payment to the Department of Labor.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. IWP shall pay to the United States the sum of Ten Million Dollars ($10,000,000), plus interest at a rate of 3.6% per annum from February 13, 2023 ("Settlement Amount"), of which $318,341.40 is restitution. Within fifteen (15) calendar days of the Effective date of this agreement, IWP shall pay One Million Two Hundred Fifty Thousand Dollars ($1,250,000), plus interest accrued.

a. Over a period of five years, IWP will pay the remaining Eight Million, Seven Hundred Fifty Thousand Dollars ($8,750,000), plus interest at 3.6% per annum, pursuant to the payment schedule attached at Exhibit A. If a prepayment occurs under either paragraph 1.d or paragraph 7 of this Agreement, the parties agree that the principal balance will be adjusted

accordingly and that the computation and allocation of interest set forth in Exhibit A will be adjusted consistant with the remaining principal balance.

b. Interest shall accrue on the unpaid Settlement Amount as indicated in Exhibit A. Collectively the Settlement Amount and interest received by the United States shall be referred to as the "Settlement Payments."

c. If IWP or any of its affiliates is sold, merged, or transferred, or a significant portion of the assets of IWP or of any of its affiliates is sold, merged, or transferred into another non-affiliated entity, IWP shall promptly notify the United States, and all remaining payments owed pursuant to the Agreement shall be accelerated and become immediately due and payable.

d. The Settlement Amount may be prepaid, in whole or in part, without penalty or premium.

e. IWP shall pay the Settlement Payments, or any portion thereof, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts.

2. No later than five business days after the Effective Date of this agreement, IWP and the DEA will enter into the Corrective Action Plan ("CAP").

3. Subject to the exceptions in Paragraph 4 (concerning reserved claims) and Paragraph 5 (injunctive relief) below, and conditioned upon the United States' receipt of the Settlement Amount, and upon IWP complying with Paragraph 2, the United States releases IWP, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under Controlled Substances Act; the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program

Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

4. Notwithstanding the release given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for failure to deliver goods or services due; and

h. Any liability for personal injury or property damages or for other consequential damages arising from the Covered Conduct.

5. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if IWP fails to pay the Settlement Amount, or fails to comply with the obligations of the CAP.

6. IWP has provided financial disclosures and supporting documents ("Financial Disclosures") to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. IWP warrants that the

Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which IWP had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy IWP's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by IWP on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by One Million Dollars ($1,000,000) or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of IWP's previously undisclosed assets. IWP agrees not to contest any collection action undertaken by the United States pursuant to this provision and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, IWP waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to IWP that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

7. In the event IWP receives proceeds from any insurance policy on account of the Settlement Amount in this Agreement or the Covered Conduct at any time before the Settlement

Amount has been paid in full, IWP agrees to remit those insurance proceeds to the United States within fifteen (15) days, and that amount shall be credited against future payments, with the schedule of remaining payments to be adjusted as described in paragraph 1.a. IWP need not remit to the United States more insurance proceeds than necessary to pay the Settlement Amount in full. This paragraph does not apply to IWP's receipt of proceeds from any insurance policy on account of its legal expenses.

8. IWP waives and shall not assert any defenses it may have to any criminal prosecution relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. IWP fully and finally releases the United States and its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that IWP has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. IWP agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of IWP, and its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement:

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) IWP's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement; and

(5) the payment IWP makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by IWP, and IWP shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, IWP shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by IWP or any of its subsidiaries or affiliates from the United States. IWP agrees that the United States, at a minimum, shall be entitled to recoup from IWP any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine IWP's books and records and to disagree with any calculations submitted by IWP or

any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by IWP, or the effect of any such Unallowable Costs on the amount of such payments.

11. The obligations imposed upon IWP pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon IWP pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

12. IWP agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, IWP shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. IWP further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. The Settlement Amount and Settlement Payments represent the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to IWP's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that IWP fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above and in Exhibit A, IWP shall be in Default of IWP's payment obligations ("Default"). The United States will provide a written Notice of

Default, and IWP shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Default will be delivered to IWP, or to such other representative as IWP shall designate in advance in writing. If IWP fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

14. In the event of Uncured Default, IWP agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by IWP to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to IWP and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, IWP agrees immediately to pay the United States the greater of (i) a

ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, IWP waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against IWP within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. IWP agrees not to contest any offset, recoupment, and/or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

15. In exchange for valuable consideration provided in this Agreement, IWP acknowledges the following:

a. IWP has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to IWP, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which IWP was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of IWP's payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, IWP or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of IWP's debts, or to adjudicate IWP as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for IWP or for all or any substantial part of IWP's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against IWP in the amount of Eleven Million Two-Hundred Twenty-Six Thousand Sixty-Two Dollars and Seventy-One Cents ($11,226,062.71), plus first payment handshake interest, per Paragraph 1, less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by a receiver, trustee, creditor, custodian, or similar official.

f. IWP agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 17.E is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. IWP shall not argue or otherwise contend that the United States' claim,

action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). IWP waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to IWP that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date.

16. This Agreement is intended to be for the benefit of the Parties only.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

20. The Agreement contains the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

21. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on IWP's successors, transferees, heirs, and assigns.

24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

26. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement ("Effective Date" of this Agreement).

SIGNATURES TO FOLLOW ON NEXT PAGE

THE UNITED STATES OF AMERICA

DATED: 6/26/2023

BY: _____

BRIAN M. LAMACCHIA
JESSICA J. WEBER
Assistant U.S. Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 6/13/2023

BY: _____

JENNIFER VALDIVIESO
Deputy Director for Program and
System Integrity
Division of Federal Employees', Longshore
and Harbor Workers' Compensation
Office of Workers' Compensation Programs
United States Department of Labor

INJURED WORKERS PHARMACY LLC

DATED: 6/23/23

BY: _____
M. Gavin
CEO

DATED: 6/23/2023

BY: _____
ERIC P. CHRISTOFFERSON
BRIAN H. BENJET
DLA Piper LLP
Counsel for Injured Workers Pharmacy LLC

Exhibit A

Year	Payment #	Due Date	Principal	Interest	Payment	Balance
						$10,000,000.00
0	1	Effective Date of Agreement	$1,250,000.00	Handshake interest to be calculated per Para. 1 based on payment date	$1,250,000.00, plus handshake interest	$8,750,000.00
1	2	One year after First Payment	$935,000.00	$315,000.00	$1,250,000.00	$7,815,000.00
2	3	Two years after First Payment	$968,660.00	$281,340.00	$1,250,000.00	$6,846,340.00
3	4	Three years after First Payment	$1,003,531.76	$246,468.24	$1,250,000.00	$5,842,808.24
4	5	Four years after First Payment	$1,039,658.90	$210,341.10	$1,250,000.00	$4,803,149.34
5	6	Five years after First Payment	$4,803,149.34	$172,913.38	$4,976,062.71	$0.00
		TOTAL	$10,000,000.00	$1,226,062.72, plus handshake interest	$11,226,062.71, plus handshake interest	

Attachment 1 - Corrective Action Plan

This Corrective Action Plan ("CAP") between the Injured Worker's Pharmacy ("IWP") and the U.S. Drug Enforcement Administration ("DEA") memorializes the policies and procedures that IWP and the DEA (jointly, the "Parties") have agreed upon to advance IWP's efforts to ensure compliance with the Controlled Substances Act (the "Act") and to enhance IWP's ability to prevent, detect, and address drug diversion. IWP is registered with the DEA as a Retail Pharmacy authorized to handle Schedule II-V controlled substances under DEA #BI7566245.

1. This CAP is incorporated by reference at paragraph 2 of the Settlement Agreement between IWP and the United States executed contemporaneously with this CAP (the "Settlement Agreement").

2. This CAP pertains to the "Covered Conduct" described in Recital H of the Settlement Agreement and in the United States' contentions in Recital I of the Settlement Agreement.

3. DEA agrees to take no further administrative action against IWP, along with their respective directors, officers, managers, employees, successors and assigns related to the Covered Conduct. However, should IWP violate this CAP, IWP understands that DEA may institute further administrative action, including but not limited to seeking revocation of IWP's DEA registration for any new violation, as well as for the Covered Conduct. DEA may also seek injunctive relief to enforce the terms of the CAP pursuant to 21 U.S.C. § 843 (f), as stated in Paragraph 5 of the Settlement Agreement.

4. The period of this CAP shall be five (5) years, starting on the Effective Date of the Settlement Agreement.

5. Whenever this CAP requires notice to the DEA, the persons to be notified will be Taylor McCarty (571-362-9087) Taylor.A.McCarty@dea.gov and Heather Danner-Ryan (571-362-9035) Heather.A.Danner-Ryan@dea.gov. Whenever this CAP requires notice to IWP, the persons to be notified will be Jayne Kresac (888-321-7945) jkresac@iwpharmacy.com and Brian Benjet (215-656-3311) brian.benjet@dlapiper.com. Either party may change the name and or contact information of its contact person(s) by so notifying the other party's contact person(s).

6. Prior to, in connection with, and following the Massachusetts AG Consent Judgment, IWP has implemented several changes to their controlled substance handling procedures, including, but not limited to, the following:

   a. In 2018, IWP released a High-Risk Prescribing Regimens Standard of Procedure ("SOP"), which requires pharmacists to conduct a thorough review of prescriptions that are identified as part of a high-risk drug combination. As later amended, this SOP requires the Pain Management Specialty Pharmacist to contact the prescribers of the identified high-risk prescriptions to confirm awareness and accuracy of the prescribed dosages and treatment plan.

   b. In 2020, IWP implemented an Initial High-Risk Opioid Prescription Policy and Procedure, which expands the clinical checks conducted prior to initial dispensing, by including a process for documenting the authenticity of high-risk prescriptions before dispensing the medication and a process for providing specific counseling to patients regarding alternatives to high-risk prescriptions. IWP also implemented training regarding the identification of initial high-risk opioid prescriptions, the review process, and the documentation process. In

addition, IWP implemented an At-Risk Patient Process that requires holistic review of patient profiles for high-risk medications.

c. IWP has implemented other new and revised pharmacy policies and procedures. IWP has provided the DEA with copies of its current policies and procedures that pertain to:

i. At-Risk Patient Chronic Pain Counseling
ii. CII Room Operation
iii. Controlled Substance Inventory
iv. Controlled Substances Workflow (CIII-CV)
v. Drug Utilization Review (DUR)
vi. Clinical Intervention: High Risk Prescribing Regimens
vii. Initial High-Risk Opioid Prescriptions
viii. Naloxone Standing Order
ix. New At-Risk Patient Auditing Procedure
x. PDMP Query
xi. Prescription Authentication Practices
xii. Processing Pharmacist Responsibilities & Preserving Pharmacist's Judgement
xiii. Professional License Verification (MedPro)
xiv. Receipt of Pharmaceutical Inventory
xv. Pharmacy Record Retention
xvi. Pharmacy Risk Evaluation and Mitigation Strategy (REMS)
xvii. Schedule II Narcotic Non-Contiguous States
xviii. PMSP Program Provider Monitoring

7. Since 2017, IWP has either hired new personnel or created new positions including: a Chief Compliance Officer that reports to the Board of Directors as well as the Chief Executive Officer, Pain Management Specialty Pharmacist, replacing its Chief Executive Officer, and hiring new executive and clinical leadership. IWP's new Chief Compliance Officer has since designed and implemented a new compliance program.

8. IWP agrees that it will continue utilizing the changes that it undertook, as those changes are listed out in paragraph 6 in order to address the Covered Conduct, and to remain in compliance with Title 21 of the Code of Federal Regulations.

9. During the CAP Period, IWP:

a. Agrees to abide by all federal, state and local statutes and regulations relating to controlled substances.

b. Agrees to allow DEA personnel to enter the registered location at any time during regular business hours, without prior notice, and without requiring DEA to obtain an administrative inspection warrant, search warrant, or other means of entry, in order to verify compliance with the Controlled Substances Act (Title 21 United States Code §801, et seq.), its implement regulations, and this CAP.

c. Agrees to maintain complete and accurate records relating to controlled substances, and to maintain copies of these records for a period of five years, from the effective date of this CAP, which will be available to DEA for inspection and copying, and inventories as required by 21 C.F.R. § 1304.04(a), except that, during the CAP Period only, the time period for which records and inventories must be maintained is extended to five (5) years from the date of such records or inventories.

d. Agrees to be truthful and accurate in all information that it submits to the DEA and that any notifications, as required by this CAP and DEA rules and regulations, are timely submitted.

e. Agrees that if any state agency or entity conducts an inspection or any investigation of IWP by seeking any records or documents from IWP, IWP hereby gives its unrestricted consent to the state agency or entity to share

any and all reports, documents, evidence and information of whatever nature or kind with the DEA.

f. Agree to continue implementing SOP's to ensure compliance with its obligations under 21 CFR 1306.04(a).

g. Agrees to maintain SOPs to ensure compliance with its obligations under 21 CFR § 1306.04(a).

h. Agrees that it shall maintain SOPs to ensure the pharmacy complies with the requirements of 21 CFR § 1306.05, including by ensuring prescriptions contain all the required information.

i. Agrees to maintain, on a current basis, a complete and accurate record of each controlled substance received, sold, delivered, dispensed or otherwise disposed of, as required by 21 CFR § 1304.21(a).

j. Agrees that only IWP pharmacists will make clinical determinations relating to Drug Utilization Review ("DUR") alerts for prescriptions that are flagged for issues such as drug interactions, potential allergic reactions, dangerous drug combinations and therapeutic duplication of opioids, to ensure that the prescribed drugs are appropriate and medically necessary prior to filling.

k. Agrees to emphasize the identification of potential safety concerns, red flags, and potentially illegitimate prescriptions.

l. Agrees to not make any decision relating to a pharmacist's performance review, compensation, promotion, work hours, hiring, or termination that relies in whole or in part on dispensing rates, whether measured individually or in aggregate. This restriction shall not be interpreted to limit IWP's ability

to reassign pharmacists to different responsibilities based on operational considerations, or to prohibit employment decisions based upon non-performance (e.g., absenteeism, failure to complete essential job responsibilities) or significant underperformance, as compared to peers and taking into account best dispensing practices.

m. Agrees to provide controlled substance training to all new employees who handle controlled substances or records related to controlled substances. This training shall be conducted within one week of hire. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

n. Agrees to provide controlled substance training to all current employees who handle controlled substances or records related to controlled substances. This training shall be conducted at least, but not limited to, annually. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.

o. Agrees to maintain a drug diversion team consisting of employees in compliance, pharmacy, security and operations roles. This drug diversion team shall be tasked with establishing, maintaining, and, if appropriate, advancing various diversion controls throughout IWP.

p. Will send a copy of this CAP, in its entirety, to the Massachusetts Department of Public Health Drug Control Program, within ten days of the full execution of this Agreement.

q. At least once every 12 months following the Effective Date of the Settlement Agreement, IWP will conduct a self-evaluation to review compliance with all requirements of the Act, this CAP and its corresponding commitments to maintain SOPs and a compliance program directed at IWP's obligations under the Act. At the completion of each evaluation, the Pharmacy Manager of Record and/or the Chief Compliance Officer will certify that he/she has completed the evaluation and document any corrective action to be taken. IWP will retain the letters of certification, and make them available to the DEA upon request, for two years following the expiration of this CAP.

r. IWP will promptly and thoroughly investigate all thefts, significant losses, and other potential diversions of controlled substances. IWP will establish protocols to reduce the number of in-transit losses of controlled substances and will promptly report all such thefts, significant losses, and other diversions to DEA. DEA is aware that IWP has additional reporting duties to licensure boards, and all other relevant agencies.

10. IWP will comply at all times with the Act and the regulations issued thereunder. To the extent that any requirements in the Act or regulations are greater than those imposed by this CAP, the stricter requirements will apply.

11. Each Party and signatory to this CAP represents that it/he/she freely and voluntarily enters into this CAP without any degree of duress or compulsion.

12. This CAP is intended for the benefit of the Parties only; it does not create any rights or benefits for third parties.

13. This CAP is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this CAP is the United States District Court for the District of Massachusetts. This CAP shall be deemed to have been drafted by both Parties and shall not, therefore, be construed against either Party in any subsequent dispute.

14. This CAP and the Settlement Agreement constitute the complete agreement between the DEA and IWP relating to the matters addressed herein. This CAP may be amended only by a writing signed by both DEA and IWP.

15. The undersigned signatories represent and warrant that it is fully authorized to execute this CAP on behalf of the parties.

16. This CAP may be executed in two counterparts, each of which constitutes an original and both of which constitute one and the same agreement.

17. This CAP is binding on IWP's successors, transferees, and assigns.

SIGNATURES TO FOLLOW ON NEXT PAGE

On Behalf of IWP:

Brian H. Benjet
DLA Piper LLP (US)
Counsel for Injured Workers Pharmacy LLC

Date: 6-23-2023

Michael Gavin
Chief Executive Officer
Injured Workers Pharmacy LLC

Date: 6/23/23

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

BRIAN BOYLE
Digitally signed by BRIAN BOYLE
Date: 2023.06.23 17:46:30 -04'00'

Brian D. Boyle
Special Agent in Charge
Drug Enforcement Administration
New England Field Division

Date:

MARK RUBBINS
Digitally signed by MARK RUBBINS
Date: 2023.06.23 15:28:23 -04'00'

Mark J. Rubbins
Diversion Program Manager
Drug Enforcement Administration
New England Field Division

Date:

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY,** **Pharmacy License No. PH02281,** **Respondent.**	**Case No. 23-428-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **INJURED WORKERS PHARMACY,** **Pharmacy License No. PH02281,** **Respondent.**	**Case No. 23-428-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR INJURED WORKERS PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

INJURED WORKERS PHARMACY
300 Federal Street
Andover, MA 01810

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5G

FILED
MAR 1 1 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **META PHARMACY SERVICES, Pharmacy License No. PH03433,** **SEAN BARCLAY, RPH, Certificate of Registration No. 17303,** **CHRISTOPHER PETERS, RPH, Certificate of Registration No. 16325, and** **MICHELLE LYNN BADTEN, RPH, Certificate of Registration No. 14966-B,** **Respondents.**	**CASE NOS. 24-125-PH-S** **24-125-RPH-A-S** **24-125-RPH-B-S** **24-125-RPH-C-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sean Barclay, RPh (Barclay), Certificate of Registration No. 17303, Respondent Christopher Peters, RPh (Peters), Certificate of Registration No. 16325, and Respondent Michelle Lynn Badten, RPh (Badten), Certificate of Registration No. 14966-B, were pharmacists registered with the Board, and Respondent Meta Pharmacy Services (Meta), Pharmacy License No. PH03433, was a pharmacy licensed by the Board.

2. On or about November 8, 2023, in case no. 23-254-PH-S, Board staff issued a cease-and-desist order with a citation and $5000 fine against Meta pursuant to NRS 639.2895 for utilizing pre-printed prescription blanks in violation of NRS 639.264(2).

FACTUAL ALLEGATIONS

3. Barclay owned Meta and acted as managing pharmacist, and Peters and Badten were employed by Meta, at the time of the events alleged herein.

4. A Board investigation in case no. 20-075-PT-S revealed that on or about March 11, 2020, Barclay hired Rosalina Ross (Ross), who held Certificate of Registration No. PT22373 as a pharmaceutical technician in training at Sunrise Pharmacy, Pharmacy License No. PH03880, in Las Vegas, without obtaining registration for Ross to work at Meta, and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta prior to her departure on or about June 22, 2020.

5. In 2021, a Board investigation in case no. 21-109-CS-S of the practice of Vincent Nalbone, MD, Certificate of Registration No. CS08907 (Nalbone), located in Las Vegas, revealed that Barclay, Peters and Badten counseled, induced and/or solicited Nalbone to issue prescriptions for controlled substances, including, without limitation, midazolam, diazepam, and alprazolam, under the names of his staff, including Hazel Mercado, Ellen Lovan, and Caroline Delos Santos, to Meta Pharmacy for the purpose of obtaining those controlled substances for office administration to multiple patients. Respondents subsequently filled and dispensed those unlawful controlled substance prescriptions to Nalbone's practice for office administration to multiple patients.

6. In 2023, a Board investigation in case no. 23-090-CS-S of the practice of Cristy O'Connell, APRN, Certificate of Registration No. CS25857, (O'Connell), located at Health

Xpress Medical Center LLC in Henderson, revealed that Barclay counseled, induced and/or solicited O'Connell to issue prescriptions for compounded semaglutide under the names of her staff and/or specific patients to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to O'Connell's practice for office administration to multiple patients.

7. In 2023, a Board investigation in case no. 23-256-CS-S of the practice of Erika Kimble, APRN, Certificate of Registration No. CS21522 (Kimble), located at Parasol Aesthetics in Las Vegas, revealed that Barclay counseled, induced and/or solicited Kimble to issue prescriptions for compounded semaglutide under the names of her staff to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to Kimble's practice for office administration to multiple patients.

8. On or about February 10, 2025, in case no. 25-008-PTT-S, Board staff issued a citation and $500 fine pursuant to NRS 639.2895 against Jasmynne Bayabo, PTT, Certificate of Registration No. PT28866 (Bayabo), for working on a expired registration from October 31, 2024, to November 20, 2024, while employed as a pharmaceutical technician in training by Meta, in violation of NRS 639.100(1), NRS 639.180 and/or NAC 639.242, and engaging in unprofessional conduct as defined in NAC 639.945(1)(i) and/or (k).

APPLICABLE LAW

9. A practitioner may prescribe a controlled substance only for a specific patient in conformance with 21 CFR § 1306.04, 21 CFR § 1306.05 and NAC 453.440 and may not issue a prescription in order to obtain controlled substances for supplying the practitioner for the

purpose of general dispensing to patients. 21 CFR § 1306.04(b); NAC 453.430(1); NRS 639.268(1)(a).

10. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a) and (c); NRS 453.331(1)(d) and (i); NRS 639.281(1); NRS 639.2813(1).

11. It is a felony offense for a pharmacist to knowingly fill or refill any prescription for a controlled substance for use by a person other than the person for whom the prescription was originally issued. 21 U.S.C. § 829; NRS 453.431(1).

12. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(1)(a).

13. A practitioner may prescribe a dangerous drug only for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

14. It is a criminal offense to falsify a prescription for a dangerous drug or otherwise purchase or possess a dangerous drug except as authorized by law. NRS 454.311(1); NRS 454.321; NRS 639.281(1); NRS 639.2813(1).

15. It is a criminal offense for a pharmacist to knowingly fill or refill any prescription for a dangerous drug for use by a person other than the person for whom the prescription was originally issued. NRS 454.231.

16. A practitioner may purchase supplies of controlled substances and/or dangerous drugs from a pharmacy, and a pharmacy may sell or otherwise provide a compounded drug to a practitioner who will be administering the drug to a patient; the quantity must not exceed the

amount necessary for the practitioner to serve the present needs of the patients of the practitioner. NRS 639.268(1)(a) and NAC 639.757(4) and (5).

17. It is unlawful to engage in practice as a pharmaceutical technician in training without a valid registration, which expires on October 31 of each even-numbered year unless timely renewed in conformances with NRS 639.180 and NAC 639.242. NRS 639.100(1).

18. Prior to amendment by LCB File No. R041-21 effective 9-29-2022, NAC 639.242(6) required a registration certificate of a pharmaceutical technician in training to specify the pharmacy of employment; termination of that employment voided the registration, and the trainee must reapply for registration before his or her services may be used by another pharmacy. Furthermore, a managing pharmacist must certify the number of hours of training a pharmaceutical technician in training has completed. NAC 639.242(6); NAC 639.245.

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

20. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

24. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

25. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act — Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

26. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

27. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS 639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Controlled Substances Act — Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

28. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violations of State Law – Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

29. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS

639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

30. By counseling, inducing and/or soliciting O'Connell and Kimble to issue unlawful prescriptions for compounded semaglutide as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violations of State Law – Filling and Dispensing Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

31. By knowingly filling and dispensing unlawful prescriptions for compounded semaglutide to the practices of O'Connell and Kimble as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

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COUNT SEVEN

Violation of State Law – Registration of Pharmaceutical Technician in Training Ross
(Respondent Barclay)

32. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta, as alleged in Paragraph 4 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NAC 639.242(6) and/or NAC 639.245 and is subject to discipline pursuant to NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Registration of Pharmaceutical Technician in Training Bayabo
(Respondent Barclay)

33. By employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NRS 639.180 and/or NAC 639.242 and is subject to discipline pursuant to NRS 639.210(12).

COUNT NINE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondents Barclay, Peters and Badten)

34. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten each were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4).

COUNT TEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties
(Respondents Barclay, Peters and Badten)

35. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten have performed their duties as registered pharmacists in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice
(Respondent Barclay)

36. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), as alleged in Paragraph 4 herein, and by employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay aided and abetted unlicensed practice, and engaged in, or aided and abetted Ross and/or Bayabo to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and/or (k), and Barclay is subject to discipline pursuant to NRS 639.210(4).

COUNT TWELVE

Managing Pharmacist Responsibility
(Respondent Barclay)

37. As the managing pharmacist of Meta at the time of the violations alleged herein, Barclay is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT THIRTEEN

Pharmacy/Pharmacy Owner Responsibility

(Respondents Barclay and Meta Pharmacy)

38. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Barclay and Meta are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration/licenses of these Respondents.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **META PHARMACY SERVICES,** **Pharmacy License No. PH03433,** **Respondent.**	**Case No. 24-125-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **META PHARMACY SERVICES,** **Pharmacy License No. PH03433,** **Respondent.**	**Case No. 24-125-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR META PHARMACY SERVICES

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Meta Pharmacy Services
8352 W WARM SPRINGS RD #120
Las Vegas, NV 89113

Joey Gilbert
405 Marsh Ave.
Reno, NV 89509

Sean Barclay, RPh
[redacted]
Las Vegas, NV [redacted]

Christopher Peters, RPh
[redacted]
Henderson, NV [redacted]

Christopher Peters, RPh c/o
Partell Specialty Pharmacy
5835 S Eastern Ave., Suite #101
Las Vegas, NV 89119

Michelle Badten, RPh
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5H

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **META PHARMACY SERVICES,** **Pharmacy License No. PH03433,** **SEAN BARCLAY, RPH,** **Certificate of Registration No. 17303,** **CHRISTOPHER PETERS, RPH,** **Certificate of Registration No. 16325, and** **MICHELLE LYNN BADTEN, RPH,** **Certificate of Registration No. 14966-B,** **Respondents.**	**CASE NOS. 24-125-PH-S** **24-125-RPH-A-S** **24-125-RPH-B-S** **24-125-RPH-C-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sean Barclay, RPh (Barclay), Certificate of Registration No. 17303, Respondent Christopher Peters, RPh (Peters), Certificate of Registration No. 16325, and Respondent Michelle Lynn Badten, RPh (Badten), Certificate of Registration No. 14966-B, were pharmacists registered with the Board, and Respondent Meta Pharmacy Services (Meta), Pharmacy License No. PH03433, was a pharmacy licensed by the Board.

2. On or about November 8, 2023, in case no. 23-254-PH-S, Board staff issued a cease-and-desist order with a citation and $5000 fine against Meta pursuant to NRS 639.2895 for utilizing pre-printed prescription blanks in violation of NRS 639.264(2).

FACTUAL ALLEGATIONS

3. Barclay owned Meta and acted as managing pharmacist, and Peters and Badten were employed by Meta, at the time of the events alleged herein.

4. A Board investigation in case no. 20-075-PT-S revealed that on or about March 11, 2020, Barclay hired Rosalina Ross (Ross), who held Certificate of Registration No. PT22373 as a pharmaceutical technician in training at Sunrise Pharmacy, Pharmacy License No. PH03880, in Las Vegas, without obtaining registration for Ross to work at Meta, and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta prior to her departure on or about June 22, 2020.

5. In 2021, a Board investigation in case no. 21-109-CS-S of the practice of Vincent Nalbone, MD, Certificate of Registration No. CS08907 (Nalbone), located in Las Vegas, revealed that Barclay, Peters and Badten counseled, induced and/or solicited Nalbone to issue prescriptions for controlled substances, including, without limitation, midazolam, diazepam, and alprazolam, under the names of his staff, including Hazel Mercado, Ellen Lovan, and Caroline Delos Santos, to Meta Pharmacy for the purpose of obtaining those controlled substances for office administration to multiple patients. Respondents subsequently filled and dispensed those unlawful controlled substance prescriptions to Nalbone's practice for office administration to multiple patients.

6. In 2023, a Board investigation in case no. 23-090-CS-S of the practice of Cristy O'Connell, APRN, Certificate of Registration No. CS25857, (O'Connell), located at Health

Xpress Medical Center LLC in Henderson, revealed that Barclay counseled, induced and/or solicited O'Connell to issue prescriptions for compounded semaglutide under the names of her staff and/or specific patients to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to O'Connell's practice for office administration to multiple patients.

7. In 2023, a Board investigation in case no. 23-256-CS-S of the practice of Erika Kimble, APRN, Certificate of Registration No. CS21522 (Kimble), located at Parasol Aesthetics in Las Vegas, revealed that Barclay counseled, induced and/or solicited Kimble to issue prescriptions for compounded semaglutide under the names of her staff to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to Kimble's practice for office administration to multiple patients.

8. On or about February 10, 2025, in case no. 25-008-PTT-S, Board staff issued a citation and $500 fine pursuant to NRS 639.2895 against Jasmynne Bayabo, PTT, Certificate of Registration No. PT28866 (Bayabo), for working on a expired registration from October 31, 2024, to November 20, 2024, while employed as a pharmaceutical technician in training by Meta, in violation of NRS 639.100(1), NRS 639.180 and/or NAC 639.242, and engaging in unprofessional conduct as defined in NAC 639.945(1)(i) and/or (k).

APPLICABLE LAW

9. A practitioner may prescribe a controlled substance only for a specific patient in conformance with 21 CFR § 1306.04, 21 CFR § 1306.05 and NAC 453.440 and may not issue a prescription in order to obtain controlled substances for supplying the practitioner for the

purpose of general dispensing to patients. 21 CFR § 1306.04(b); NAC 453.430(1); NRS 639.268(1)(a).

10. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a) and (c); NRS 453.331(1)(d) and (i); NRS 639.281(1); NRS 639.2813(1).

11. It is a felony offense for a pharmacist to knowingly fill or refill any prescription for a controlled substance for use by a person other than the person for whom the prescription was originally issued. 21 U.S.C. § 829; NRS 453.431(1).

12. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

13. A practitioner may prescribe a dangerous drug only for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

14. It is a criminal offense to falsify a prescription for a dangerous drug or otherwise purchase or possess a dangerous drug except as authorized by law. NRS 454.311(1); NRS 454.321; NRS 639.281(1); NRS 639.2813(1).

15. It is a criminal offense for a pharmacist to knowingly fill or refill any prescription for a dangerous drug for use by a person other than the person for whom the prescription was originally issued. NRS 454.231.

16. A practitioner may purchase supplies of controlled substances and/or dangerous drugs from a pharmacy, and a pharmacy may sell or otherwise provide a compounded drug to a practitioner who will be administering the drug to a patient; the quantity must not exceed the

amount necessary for the practitioner to serve the present needs of the patients of the practitioner. NRS 639.268(1)(a) and NAC 639.757(4) and (5).

17. It is unlawful to engage in practice as a pharmaceutical technician in training without a valid registration, which expires on October 31 of each even-numbered year unless timely renewed in conformances with NRS 639.180 and NAC 639.242. NRS 639.100(1).

18. Prior to amendment by LCB File No. R041-21 effective 9-29-2022, NAC 639.242(6) required a registration certificate of a pharmaceutical technician in training to specify the pharmacy of employment; termination of that employment voided the registration, and the trainee must reapply for registration before his or her services may be used by another pharmacy. Furthermore, a managing pharmacist must certify the number of hours of training a pharmaceutical technician in training has completed. NAC 639.242(6); NAC 639.245.

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

20. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

24. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

25. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act — Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

26. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

27. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS 639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Controlled Substances Act — Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

28. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violations of State Law – Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

29. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS

639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

30. By counseling, inducing and/or soliciting O'Connell and Kimble to issue unlawful prescriptions for compounded semaglutide as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violations of State Law – Filling and Dispensing Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

31. By knowingly filling and dispensing unlawful prescriptions for compounded semaglutide to the practices of O'Connell and Kimble as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

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COUNT SEVEN

Violation of State Law – Registration of Pharmaceutical Technician in Training Ross
(Respondent Barclay)

32. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta, as alleged in Paragraph 4 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NAC 639.242(6) and/or NAC 639.245 and is subject to discipline pursuant to NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Registration of Pharmaceutical Technician in Training Bayabo
(Respondent Barclay)

33. By employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NRS 639.180 and/or NAC 639.242 and is subject to discipline pursuant to NRS 639.210(12).

COUNT NINE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondents Barclay, Peters and Badten)

34. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten each were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4).

COUNT TEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties
(Respondents Barclay, Peters and Badten)

35. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten have performed their duties as registered pharmacists in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice
(Respondent Barclay)

36. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), as alleged in Paragraph 4 herein, and by employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay aided and abetted unlicensed practice, and engaged in, or aided and abetted Ross and/or Bayabo to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and/or (k), and Barclay is subject to discipline pursuant to NRS 639.210(4).

COUNT TWELVE

Managing Pharmacist Responsibility
(Respondent Barclay)

37. As the managing pharmacist of Meta at the time of the violations alleged herein, Barclay is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT THIRTEEN

Pharmacy/Pharmacy Owner Responsibility

(Respondents Barclay and Meta Pharmacy)

38. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Barclay and Meta are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration/licenses of these Respondents.

Signed this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN BARCLAY, RPH,** **Certificate of Registration No. 17303,** **Respondent.**	**Case No. 24-125-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SEAN BARCLAY, RPH,** **Certificate of Registration No. 17303,** **Respondent.**	**Case No. 24-125-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

SEAN BARCLAY, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Meta Pharmacy Services
8352 W WARM SPRINGS RD #120
Las Vegas, NV 89113

Joey Gilbert
405 Marsh Ave.
Reno, NV 89509

Sean Barclay, RPh
[redacted]
Las Vegas, NV [redacted]

Christopher Peters, RPh
[redacted]
Henderson, NV [redacted]

Christopher Peters, RPh c/o
Partell Specialty Pharmacy
5835 S Eastern Ave., Suite #101
Las Vegas, NV 89119

Michelle Badten, RPh
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
MAR 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

META PHARMACY SERVICES,
Pharmacy License No. PH03433,

SEAN BARCLAY, RPH,
Certificate of Registration No. 17303,

CHRISTOPHER PETERS, RPH,
Certificate of Registration No. 16325, and

MICHELLE LYNN BADTEN, RPH,
Certificate of Registration No. 14966-B,

Respondents.

CASE NOS. 24-125-PH-S
24-125-RPH-A-S
24-125-RPH-B-S
24-125-RPH-C-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sean Barclay, RPh (Barclay), Certificate of Registration No. 17303, Respondent Christopher Peters, RPh (Peters), Certificate of Registration No. 16325, and Respondent Michelle Lynn Badten, RPh (Badten), Certificate of Registration No. 14966-B, were pharmacists registered with the Board, and Respondent Meta Pharmacy Services (Meta), Pharmacy License No. PH03433, was a pharmacy licensed by the Board.

2. On or about November 8, 2023, in case no. 23-254-PH-S, Board staff issued a cease-and-desist order with a citation and $5000 fine against Meta pursuant to NRS 639.2895 for utilizing pre-printed prescription blanks in violation of NRS 639.264(2).

FACTUAL ALLEGATIONS

3. Barclay owned Meta and acted as managing pharmacist, and Peters and Badten were employed by Meta, at the time of the events alleged herein.

4. A Board investigation in case no. 20-075-PT-S revealed that on or about March 11, 2020, Barclay hired Rosalina Ross (Ross), who held Certificate of Registration No. PT22373 as a pharmaceutical technician in training at Sunrise Pharmacy, Pharmacy License No. PH03880, in Las Vegas, without obtaining registration for Ross to work at Meta, and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta prior to her departure on or about June 22, 2020.

5. In 2021, a Board investigation in case no. 21-109-CS-S of the practice of Vincent Nalbone, MD, Certificate of Registration No. CS08907 (Nalbone), located in Las Vegas, revealed that Barclay, Peters and Badten counseled, induced and/or solicited Nalbone to issue prescriptions for controlled substances, including, without limitation, midazolam, diazepam, and alprazolam, under the names of his staff, including Hazel Mercado, Ellen Lovan, and Caroline Delos Santos, to Meta Pharmacy for the purpose of obtaining those controlled substances for office administration to multiple patients. Respondents subsequently filled and dispensed those unlawful controlled substance prescriptions to Nalbone's practice for office administration to multiple patients.

6. In 2023, a Board investigation in case no. 23-090-CS-S of the practice of Cristy O'Connell, APRN, Certificate of Registration No. CS25857, (O'Connell), located at Health

Xpress Medical Center LLC in Henderson, revealed that Barclay counseled, induced and/or solicited O'Connell to issue prescriptions for compounded semaglutide under the names of her staff and/or specific patients to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to O'Connell's practice for office administration to multiple patients.

7. In 2023, a Board investigation in case no. 23-256-CS-S of the practice of Erika Kimble, APRN, Certificate of Registration No. CS21522 (Kimble), located at Parasol Aesthetics in Las Vegas, revealed that Barclay counseled, induced and/or solicited Kimble to issue prescriptions for compounded semaglutide under the names of her staff to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to Kimble's practice for office administration to multiple patients.

8. On or about February 10, 2025, in case no. 25-008-PTT-S, Board staff issued a citation and $500 fine pursuant to NRS 639.2895 against Jasmynne Bayabo, PTT, Certificate of Registration No. PT28866 (Bayabo), for working on a expired registration from October 31, 2024, to November 20, 2024, while employed as a pharmaceutical technician in training by Meta, in violation of NRS 639.100(1), NRS 639.180 and/or NAC 639.242, and engaging in unprofessional conduct as defined in NAC 639.945(1)(i) and/or (k).

APPLICABLE LAW

9. A practitioner may prescribe a controlled substance only for a specific patient in conformance with 21 CFR § 1306.04, 21 CFR § 1306.05 and NAC 453.440 and may not issue a prescription in order to obtain controlled substances for supplying the practitioner for the

purpose of general dispensing to patients. 21 CFR § 1306.04(b); NAC 453.430(1); NRS 639.268(1)(a).

10. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a) and (c); NRS 453.331(1)(d) and (i); NRS 639.281(1); NRS 639.2813(1).

11. It is a felony offense for a pharmacist to knowingly fill or refill any prescription for a controlled substance for use by a person other than the person for whom the prescription was originally issued. 21 U.S.C. § 829; NRS 453.431(1).

12. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

13. A practitioner may prescribe a dangerous drug only for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

14. It is a criminal offense to falsify a prescription for a dangerous drug or otherwise purchase or possess a dangerous drug except as authorized by law. NRS 454.311(1); NRS 454.321; NRS 639.281(1); NRS 639.2813(1).

15. It is a criminal offense for a pharmacist to knowingly fill or refill any prescription for a dangerous drug for use by a person other than the person for whom the prescription was originally issued. NRS 454.231.

16. A practitioner may purchase supplies of controlled substances and/or dangerous drugs from a pharmacy, and a pharmacy may sell or otherwise provide a compounded drug to a practitioner who will be administering the drug to a patient; the quantity must not exceed the

amount necessary for the practitioner to serve the present needs of the patients of the practitioner. NRS 639.268(1)(a) and NAC 639.757(4) and (5).

17. It is unlawful to engage in practice as a pharmaceutical technician in training without a valid registration, which expires on October 31 of each even-numbered year unless timely renewed in conformances with NRS 639.180 and NAC 639.242. NRS 639.100(1).

18. Prior to amendment by LCB File No. R041-21 effective 9-29-2022, NAC 639.242(6) required a registration certificate of a pharmaceutical technician in training to specify the pharmacy of employment; termination of that employment voided the registration, and the trainee must reapply for registration before his or her services may be used by another pharmacy. Furthermore, a managing pharmacist must certify the number of hours of training a pharmaceutical technician in training has completed. NAC 639.242(6); NAC 639.245.

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

20. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

24. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

25. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act — Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

26. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

27. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS 639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Controlled Substances Act — Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

28. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violations of State Law – Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

29. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS

639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

30. By counseling, inducing and/or soliciting O'Connell and Kimble to issue unlawful prescriptions for compounded semaglutide as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violations of State Law – Filling and Dispensing Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

31. By knowingly filling and dispensing unlawful prescriptions for compounded semaglutide to the practices of O'Connell and Kimble as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

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COUNT SEVEN

Violation of State Law – Registration of Pharmaceutical Technician in Training Ross
(Respondent Barclay)

32. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta, as alleged in Paragraph 4 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NAC 639.242(6) and/or NAC 639.245 and is subject to discipline pursuant to NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Registration of Pharmaceutical Technician in Training Bayabo
(Respondent Barclay)

33. By employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NRS 639.180 and/or NAC 639.242 and is subject to discipline pursuant to NRS 639.210(12).

COUNT NINE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondents Barclay, Peters and Badten)

34. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten each were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4).

COUNT TEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties
(Respondents Barclay, Peters and Badten)

35. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten have performed their duties as registered pharmacists in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice
(Respondent Barclay)

36. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), as alleged in Paragraph 4 herein, and by employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay aided and abetted unlicensed practice, and engaged in, or aided and abetted Ross and/or Bayabo to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and/or (k), and Barclay is subject to discipline pursuant to NRS 639.210(4).

COUNT TWELVE

Managing Pharmacist Responsibility
(Respondent Barclay)

37. As the managing pharmacist of Meta at the time of the violations alleged herein, Barclay is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT THIRTEEN

Pharmacy/Pharmacy Owner Responsibility

(Respondents Barclay and Meta Pharmacy)

38. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Barclay and Meta are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration/licenses of these Respondents.

Signed this 12th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHRISTOPHER PETERS, RPH,** **Certificate of Registration No. 16325,** **Respondent.**	**Case No. 24-125-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHRISTOPHER PETERS, RPH,** **Certificate of Registration No. 16325,** **Respondent.**	**Case No. 24-125-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

CHRISTOPHER PETERS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Meta Pharmacy Services
8352 W WARM SPRINGS RD #120
Las Vegas, NV 89113

Joey Gilbert
405 Marsh Ave.
Reno, NV 89509

Sean Barclay, RPh
[redacted]
Las Vegas, NV [redacted]

Christopher Peters, RPh
[redacted]
Henderson, NV [redacted]

Christopher Peters, RPh c/o
Partell Specialty Pharmacy
5835 S Eastern Ave., Suite #101
Las Vegas, NV 89119

Michelle Badten, RPh
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5J

FILED
MAR 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **META PHARMACY SERVICES, Pharmacy License No. PH03433,** **SEAN BARCLAY, RPH, Certificate of Registration No. 17303,** **CHRISTOPHER PETERS, RPH, Certificate of Registration No. 16325, and** **MICHELLE LYNN BADTEN, RPH, Certificate of Registration No. 14966-B,** **Respondents.**	**CASE NOS. 24-125-PH-S** **24-125-RPH-A-S** **24-125-RPH-B-S** **24-125-RPH-C-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Sean Barclay, RPh (Barclay), Certificate of Registration No. 17303, Respondent Christopher Peters, RPh (Peters), Certificate of Registration No. 16325, and Respondent Michelle Lynn Badten, RPh (Badten), Certificate of Registration No. 14966-B, were pharmacists registered with the Board, and Respondent Meta Pharmacy Services (Meta), Pharmacy License No. PH03433, was a pharmacy licensed by the Board.

2. On or about November 8, 2023, in case no. 23-254-PH-S, Board staff issued a cease-and-desist order with a citation and $5000 fine against Meta pursuant to NRS 639.2895 for utilizing pre-printed prescription blanks in violation of NRS 639.264(2).

FACTUAL ALLEGATIONS

3. Barclay owned Meta and acted as managing pharmacist, and Peters and Badten were employed by Meta, at the time of the events alleged herein.

4. A Board investigation in case no. 20-075-PT-S revealed that on or about March 11, 2020, Barclay hired Rosalina Ross (Ross), who held Certificate of Registration No. PT22373 as a pharmaceutical technician in training at Sunrise Pharmacy, Pharmacy License No. PH03880, in Las Vegas, without obtaining registration for Ross to work at Meta, and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta prior to her departure on or about June 22, 2020.

5. In 2021, a Board investigation in case no. 21-109-CS-S of the practice of Vincent Nalbone, MD, Certificate of Registration No. CS08907 (Nalbone), located in Las Vegas, revealed that Barclay, Peters and Badten counseled, induced and/or solicited Nalbone to issue prescriptions for controlled substances, including, without limitation, midazolam, diazepam, and alprazolam, under the names of his staff, including Hazel Mercado, Ellen Lovan, and Caroline Delos Santos, to Meta Pharmacy for the purpose of obtaining those controlled substances for office administration to multiple patients. Respondents subsequently filled and dispensed those unlawful controlled substance prescriptions to Nalbone's practice for office administration to multiple patients.

6. In 2023, a Board investigation in case no. 23-090-CS-S of the practice of Cristy O'Connell, APRN, Certificate of Registration No. CS25857, (O'Connell), located at Health

Xpress Medical Center LLC in Henderson, revealed that Barclay counseled, induced and/or solicited O'Connell to issue prescriptions for compounded semaglutide under the names of her staff and/or specific patients to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to O'Connell's practice for office administration to multiple patients.

7. In 2023, a Board investigation in case no. 23-256-CS-S of the practice of Erika Kimble, APRN, Certificate of Registration No. CS21522 (Kimble), located at Parasol Aesthetics in Las Vegas, revealed that Barclay counseled, induced and/or solicited Kimble to issue prescriptions for compounded semaglutide under the names of her staff to Meta Pharmacy for the purpose of obtaining compounded semaglutide for office administration to multiple patients. Barclay subsequently filled and dispensed those unlawful prescriptions for compounded semaglutide to Kimble's practice for office administration to multiple patients.

8. On or about February 10, 2025, in case no. 25-008-PTT-S, Board staff issued a citation and $500 fine pursuant to NRS 639.2895 against Jasmynne Bayabo, PTT, Certificate of Registration No. PT28866 (Bayabo), for working on a expired registration from October 31, 2024, to November 20, 2024, while employed as a pharmaceutical technician in training by Meta, in violation of NRS 639.100(1), NRS 639.180 and/or NAC 639.242, and engaging in unprofessional conduct as defined in NAC 639.945(1)(i) and/or (k).

APPLICABLE LAW

9. A practitioner may prescribe a controlled substance only for a specific patient in conformance with 21 CFR § 1306.04, 21 CFR § 1306.05 and NAC 453.440 and may not issue a prescription in order to obtain controlled substances for supplying the practitioner for the

purpose of general dispensing to patients. 21 CFR § 1306.04(b); NAC 453.430(1); NRS 639.268(1)(a).

10. It is a felony offense to falsify a prescription for a controlled substance or otherwise purchase or possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a) and (c); NRS 453.331(1)(d) and (i); NRS 639.281(1); NRS 639.2813(1).

11. It is a felony offense for a pharmacist to knowingly fill or refill any prescription for a controlled substance for use by a person other than the person for whom the prescription was originally issued. 21 U.S.C. § 829; NRS 453.431(1).

12. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

13. A practitioner may prescribe a dangerous drug only for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

14. It is a criminal offense to falsify a prescription for a dangerous drug or otherwise purchase or possess a dangerous drug except as authorized by law. NRS 454.311(1); NRS 454.321; NRS 639.281(1); NRS 639.2813(1).

15. It is a criminal offense for a pharmacist to knowingly fill or refill any prescription for a dangerous drug for use by a person other than the person for whom the prescription was originally issued. NRS 454.231.

16. A practitioner may purchase supplies of controlled substances and/or dangerous drugs from a pharmacy, and a pharmacy may sell or otherwise provide a compounded drug to a practitioner who will be administering the drug to a patient; the quantity must not exceed the

amount necessary for the practitioner to serve the present needs of the patients of the practitioner. NRS 639.268(1)(a) and NAC 639.757(4) and (5).

17. It is unlawful to engage in practice as a pharmaceutical technician in training without a valid registration, which expires on October 31 of each even-numbered year unless timely renewed in conformances with NRS 639.180 and NAC 639.242. NRS 639.100(1).

18. Prior to amendment by LCB File No. R041-21 effective 9-29-2022, NAC 639.242(6) required a registration certificate of a pharmaceutical technician in training to specify the pharmacy of employment; termination of that employment voided the registration, and the trainee must reapply for registration before his or her services may be used by another pharmacy. Furthermore, a managing pharmacist must certify the number of hours of training a pharmaceutical technician in training has completed. NAC 639.242(6); NAC 639.245.

19. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

20. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

24. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

25. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Controlled Substances Act — Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

26. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

27. By counseling, inducing and/or soliciting Nalbone to issue unlawful prescriptions for controlled substances as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS 639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Controlled Substances Act — Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

28. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 829, 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR 1306.04 and/or 21 CFR 1306.05, and are subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violations of State Law – Filling and Dispensing Unlawful Controlled Substance Prescriptions

(Respondents Barclay, Peters and Badten)

29. By knowingly filling and dispensing unlawful prescriptions for controlled substances to Nalbone's practice as alleged in Paragraph 5 herein, Barclay, Peters and Badten violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.321(1)(a) and (c), NRS 453.331(1)(d) and (i), NRS 453.431(1), NRS 639.268(1)(a), NRS

639.281(1), NRS 639.2813(1), NAC 453.440 and/or NAC 639.757(4) and (5), and are subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Violations of State Law – Aiding and Abetting/Conspiring to Issue Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

30. By counseling, inducing and/or soliciting O'Connell and Kimble to issue unlawful prescriptions for compounded semaglutide as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violations of State Law – Filling and Dispensing Unlawful Compounded Drug Prescriptions

(Respondent Barclay)

31. By knowingly filling and dispensing unlawful prescriptions for compounded semaglutide to the practices of O'Connell and Kimble as alleged in Paragraphs 6 and 7 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.231, NRS 454.311(1), NRS 454.321, NRS 639.2353, NRS 639.281(1); NRS 639.2813(1) and/or NAC 639.757(4) and (5), and is subject to discipline pursuant to NRS 639.210(12).

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COUNT SEVEN

Violation of State Law – Registration of Pharmaceutical Technician in Training Ross
(Respondent Barclay)

32. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), and subsequently submitted documentation falsely certifying the number of hours of training Ross completed at Meta, as alleged in Paragraph 4 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NAC 639.242(6) and/or NAC 639.245 and is subject to discipline pursuant to NRS 639.210(12).

COUNT EIGHT

Violation of State Law – Registration of Pharmaceutical Technician in Training Bayabo
(Respondent Barclay)

33. By employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NRS 639.180 and/or NAC 639.242 and is subject to discipline pursuant to NRS 639.210(12).

COUNT NINE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction
(Respondents Barclay, Peters and Badten)

34. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten each were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4).

COUNT TEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties
(Respondents Barclay, Peters and Badten)

35. By their conduct as alleged in Paragraphs 4-8 herein, Barclay, Peters and Badten have performed their duties as registered pharmacists in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT ELEVEN

Unprofessional Conduct – Aiding and Abetting Unlicensed Practice
(Respondent Barclay)

36. By employing Ross as a pharmaceutical technician in training without obtaining registration for Ross to work at Meta in compliance with former NAC 639.242(6), as alleged in Paragraph 4 herein, and by employing Bayabo as a pharmaceutical technician in training at Meta on an expired registration from October 31, 2024, to November 20, 2024, as alleged in Paragraph 8 herein, Barclay aided and abetted unlicensed practice, and engaged in, or aided and abetted Ross and/or Bayabo to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and/or (k), and Barclay is subject to discipline pursuant to NRS 639.210(4).

COUNT TWELVE

Managing Pharmacist Responsibility
(Respondent Barclay)

37. As the managing pharmacist of Meta at the time of the violations alleged herein, Barclay is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT THIRTEEN

Pharmacy/Pharmacy Owner Responsibility

(Respondents Barclay and Meta Pharmacy)

38. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Barclay and Meta are responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration/licenses of these Respondents.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHELLE LYNN BADTEN, RPH,** **Certificate of Registration No. 14966-B,** **Respondent.**	**Case No. 24-125-RPH-C-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHELLE LYNN BADTEN, RPH,** **Certificate of Registration No. 14966-B,** **Respondent.**	**Case No. 24-125-RPH-C-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

MICHELLE LYNN BADTEN, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Meta Pharmacy Services
8352 W WARM SPRINGS RD #120
Las Vegas, NV 89113

Joey Gilbert
405 Marsh Ave.
Reno, NV 89509

Sean Barclay, RPh
[redacted]
Las Vegas, NV [redacted]

Christopher Peters, RPh
[redacted]
Henderson, NV [redacted]

Christopher Peters, RPh c/o
Partell Specialty Pharmacy
5835 S Eastern Ave., Suite #101
Las Vegas, NV 89119

Michelle Badten, RPh
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
MAR 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**CASE NO. 24-470-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Abdollah Assad, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS12432, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about August 14, 2024, the Nevada State Board of Medical Examiners (NSBME) filed charges in Case Nos 24-28982-1 and 24-28982-2 against Respondent's License No. 10883 to practice medicine for engaging in conduct in violation of NRS Chapter 630.

3. Respondent failed to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432.

4. Respondent failed to review the patient utilization report for patient S.D. in the Prescription Monitoring Program (PMP) database prior to issuing a prescription for Adderall, a

Schedule II controlled substance, on August 18, 2024. Respondent subsequently changed the dosage of patient S.D.'s Adderall prescription from 20mg to 30mg on September 9, 2024, and again prescribed Adderall to S.D. on September 19, 2024, each time without reviewing the patient utilization report for patient S.D. in the PMP database.

APPLICABLE LAW

5. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

6. A prescribing practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

7. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

9. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

10. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

11. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Furnishing False Material Information to Board

12. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432, as detailed in Paragraphs 2 and 3 herein, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO

Obtaining Registration by False or Fraudulent Application

13. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS12432, as detailed in Paragraphs 2 and 3 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE

Violation of State Law when Prescribing a Controlled Substance

14. By failing to review the patient utilization report for patient S.D. in the PMP database prior to issuing controlled substance prescriptions, as detailed in Paragraph 4 herein, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

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COUNT FOUR

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By failed to review the patient utilization report for patient S.D. in the PMP database prior to issuing controlled substance prescriptions, as detailed in Paragraph 4 herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By failing to disclose to the Board the pending charges in NSBME Case Nos 24-28982-1 and 24-28982-2 on his 2024 biennial renewal application for Certificate of Registration No. CS124321, and by violating NRS 639.23507, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**Case No. 24-470-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432,** **Respondent.**	**Case No. 24-470-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

Abdollah Assad, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Abdollah Assad, MD
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee :	$200.00
Convenience Fee :	$10.00
License Number :	CS12432
License Type :	Controlled Substance
New Expiration Date :	10/31/2026

Personal Information

First Name : ABDOLLAH

Middle (initial only) :

Last Name : ASSAD

License # : CS12432

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA :

Military Address : ☐

Street : [redacted]

Country : United States

City : RENO State : Nevada Zip : [redacted]

Practice Phone : (XXX) XXX-XXXX

Cell Phone : [redacted]

Email Address : [redacted]

Sex : Male

Child Support Information – Check appropriate answer

- ◉ I am **NOT SUBJECT** to a court order for the support of a child.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ○ I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.
- ○ Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)
- ○ Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	○ Yes ◉ No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	○ Yes ◉ No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	○ Yes ◉ No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? ○ Yes ◉ No

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ○ Yes ◉ No

DEA Registration

Please upload a copy of your current DEA Registration associated with the Controlled Substance Registration you are renewing.

Document Name	Document Type	Date	Link	Action
nevada pharmacy license 2020 to 2022	NV DEA Certificate	10/25/2024	Document Details	

Document Name :

Document Type : NV DEA Certificate

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload | Cancel

Acknowledgement and Declaration

☑ I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

By signing and submitting this renewal application, I certify that: 1. I hold an active and current Nevada license with my professional licensing board, and 2. My DEA certificate is CURRENT and reflects my current NV practicing address.

Signature : abdollah assad

Date Of Application : 10/25/2024

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2024 to 10/31/2026	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : 120716454457

InvoiceDate : 10/25/2024

Paid

Pay & Submit

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **ABDOLLAH ASSAD, M.D.,** **Respondent.**	**Case No. 24-28982-1**

FILED

AUG 14 2024

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [signature]

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, Senior Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Abdollah Assad, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor holding an active license to practice medicine in the State of Nevada (License No. 10883). Respondent was originally licensed by the Board on April 8, 2004.

2. Patient A[2] was a thirty-one (31) year-old female at the time of the events at issue.

3. During the relevant time period, Patient A was a long-established psychiatric patient of Respondent, having regular visits being under Respondent's care and treatment since June 23, 2011. During these regular visits, Respondent documented a history of anxiety and problematic relationships that included her difficult relationship with her boyfriend on repeated occasions. Respondent's records from these visits are handwritten and largely illegible.

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Chowdhury H. Ahsan, M.D., Ph.D, FACC, Ms. Pamela J. Beal and Irwin B. Simon, M.D., FACS.

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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4. On September 28, 2020, Respondent documented a telephone visit with Patient A who informed Respondent that she was moving out of the state. During this telephone visit, Respondent prescribed Latuda, Xanax, and Adderall for her.

5. On or about October 12, 2020, Respondent was contacted by Patient A who was staying in a motel and admitted to having attempted suicide. Respondent did not instruct Patient A to go to an emergency room, call an ambulance, or call police but instead came to the motel and picked up Patient A.

6. Respondent did not take Patient A to the hospital, nor attempt to initiate a legal 2000 mandatory hold to observe Patient A after her attempted suicide. Instead, Respondent took Patient A to another motel, and engaged in sexual intercourse with her, despite his awareness of troublesome relationships in the past and her obvious fragile state.

7. On October 16, 2020, following the sexual encounter, Respondent continued to prescribe Adderall to Patient A, and documented that Patient A was going to seek a new physician. Respondent did not refer Patient A to a new psychiatrist or make arrangements for the transfer of her care.

COUNT I

NRS 630.301(4) - Malpractice

8. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

9. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

10. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

11. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A by engaging in sexual intercourse and having an

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inappropriate sexual relationship with Patient A while still continuing to see her as his patient and prescribe her Adderall.

12. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.304(5) – Influencing a Patient to Engage in Sexual Activity

13. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

14. NRS 630.304(5) provides that influencing a patient in order to engage in sexual activity with the patient or others is grounds for initiating disciplinary action.

15. As demonstrated by, but not limited to, the above-outlined facts, Respondent influenced Patient A by failing to properly admit her to an appropriate care facility or get Patient A emergency assistance following a suicide attempt despite her documented history of troubled relationships, but instead took Patient A to a motel and engaged in sexual intercourse with her.

16. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.301(5) – Engaging in Sexual Activity with a Patient

17. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

18. NRS 630.301(5) provides that engaging by a practitioner in any sexual activity with a patient who is currently being treated by the practitioner constitutes grounds for initiating disciplinary action.

19. As demonstrated by, but not limited to, the above-outlined facts, Respondent engaged in sexual intercourse with Patient A and subsequently continued to prescribe controlled substances to her as her physician.

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(775) 688-2559

20. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.306(1)(p) - Unsafe or Unprofessional Conduct

21. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

22. Engaging in any act that is unsafe or unprofessional conduct in accordance with regulations adopted by the Board is grounds for disciplinary action against a licensee pursuant to NRS 630.306(1)(p).

23. As demonstrated by, but not limited to, the above-outlined facts, Respondent's conduct was unprofessional and violated the physician-patient relationship when Respondent engaged in sexual intercourse with Patient A, a vulnerable psychiatric patient.

24. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT V

NRS 630.304(7) - Terminating Medical Care without Adequate Notice to a Patient

25. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

26. NRS 630.304(7) provides that terminating the medical care of a patient without adequate notice or without making other arrangements for the continued care of the patient is grounds for initiating disciplinary action.

27. Respondent terminated the medical care of Patient A without adequate notice when he discontinued care of Patient A on October 16, 2020. Respondent noted Patient A's intention to seek another provider but failed to coordinate her care or provide a referral to an appropriate physician following his October 16, 2020, prescription of Adderall.

28. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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COUNT VI

NRS 630.301(7) – Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain

29. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

30. NRS 630.301(7) provides that "engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain" is grounds for initiating discipline against a licensee.

31. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated the trust of a patient and exploited the relationship between the Respondent and Patient A by gaining intimate knowledge of Patient A during psychiatric treatment, and subsequently engaging in a sexual relationship with Patient A while she was in a vulnerable state.

32. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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Reno, Nevada 89521
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6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Chowdhury H. Ahsan, M.D., Ph.D., FACC, having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
CHOWDHURY H. AHSAN, M.D., PH.D., FACC
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **ABDOLLAH ASSAD, M.D.,** **Respondent.**	**Case No. 24-28982-2** **FILED** AUG 14 2024 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
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COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, Senior Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Abdollah Assad, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor holding an active license to practice medicine in the State of Nevada (License No. 10883). Respondent was originally licensed by the Board on April 8, 2004.

2. Patient A[2] was a thirty-three (33) year-old male at the time of the events at issue.

3. On July 3, 2019, Patient A began seeing Respondent to continue medication-assisted treatment following the retirement of a psychiatrist he had been seeing regularly for the issue. Respondent diagnosed Patient A with opioid dependence but did not include a comprehensive assessment, review or records from Patient A's previous provider. Respondent also failed to collect other pertinent information to support a comprehensive diagnosis or

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Chowdhury H. Ahsan, M.D., Ph.D, FACC, Ms. Pamela J. Beal and Irwin B. Simon, M.D., FACS.

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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treatment plan. Respondent then prescribed Patient A buprenorphine, but did not document any evidence that a discussion about informed consent took place prior to the prescription of controlled substances to Patient A.

4. On August 20, 2019, Respondent prescribed Patient A Risperdal, an antipsychotic medication. Respondent did not include a review of prior records, any documentation, nor any comprehensive examination in his records to support a diagnosis of a psychiatric disorder that would justify prescribing Risperdal. Moreover, Respondent also failed to document whether Patient A received informed consent or alternatives to Risperdal prior to delivery of the prescription.

5. On November 6, 2019, Respondent prescribed Patient A Zoloft, an SSRI antidepressant. Respondent did not include any documentation or examination in his records to support an appropriate diagnosis of depression that justifies the prescription for Zoloft, nor did Respondent document that Patient A received informed consent or alternatives to Zoloft prior to delivery of the prescription.

6. In total, Respondent saw Patient A from July 7, 2019, through January 8, 2020. Throughout Patient A's treatment, Respondent did not include documentation that he checked Patient A's Prescription Monitoring Program (PMP) report prior to prescribing Patient A controlled substances in violation of Nevada law, especially given Patient A's history of medication dependence.

7. Throughout Respondent's treatment of Patient A, Respondent required urine drug screenings which required Patient A to pay out-of-pocket for the tests despite having Medicare. Respondent did not have a valid Clinical Laboratory Improvements Amendment (CLIA) waiver for the point-of-care testing offered in his practice to charge payments to his patients.

8. On January 8, 2020, Patient A was noted by Respondent to be a "no call, no show" whereupon Respondent ceased his medical care of Patient A. Respondent documents no further effort to contact Patient A or refer him to an appropriate clinician to maintain his prescription.

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OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
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(775) 688-2559

COUNT I

NRS 630.301(4) - Malpractice

9. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

10. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

11. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

12. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A by failing to either document or perform an appropriate psychological examination or perform a review of Patient A's prior medical records to support the diagnosis of opioid dependence, and to provide the prescription of controlled substances.

13. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Complete Medical Records

14. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

15. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

16. Respondent failed to maintain complete medical records relating to the diagnosis, treatment and care of Patient A, by failing to correctly document his actions when he treated Patient A, whose medical records were not timely, legible, accurate, and complete as evidenced by Respondent's handwritten and illegible medical records for Patient A's care which omits standard

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portions of psychological examinations including an appropriate review of symptoms, and informed consent.

17. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.304(7) - Terminating Medical Care without Adequate Notice to a Patient

18. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

19. NRS 630.304(7) provides that terminating the medical care of a patient without adequate notice or without making other arrangements for the continued care of the patient is grounds for initiating disciplinary action.

20. Respondent terminated the medical care of Patient A without adequate notice to Patient A and without making any arrangements for Patient A's continued care after January 8, 2020, when Respondent failed to appropriately follow-up or refer Patient A to another medical care provider after the termination of his care. Furthermore, Respondent failed to document his termination treatment for Patient A.

21. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT IV

NRS 630.306(1)(b)(2) - Violation of Standards of Practice – Violation of Model Policy

22. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

23. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

24. The Board adopted by reference the Model Policy in NAC 630.187.

25. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

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Reno, Nevada 89521
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26. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions to Patient A for opioid analgesics to treat chronic pain in a manner that deviated from the Model Policy by failing to check Patient A's PMP report at any time during the course of Patient A's treatment.

27. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT V

NRS 630.306(1)(b)(2) - Violation of Standards of Practice Established by Regulation – Unreasonable Additional Charges for Laboratory Tests

28. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

29. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

30. NAC 630.230(1)(f) provides that a physician shall not, "Make an unreasonable additional charge for tests in a laboratory"

31. Respondent charged cash payments to Patient A for laboratory testing covered by Medicare in violation of Medicare policies without having a valid CLIA Waiver.

32. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

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4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Chowdhury H. Ahsan, M.D., Ph.D., FACC, having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
CHOWDHURY H. AHSAN, M.D., PH.D., FACC
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

FILED
APR -1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABDOLLAH ASSAD, MD,** **Certificate of Registration No. CS12432** **Respondent.**	**Case No. 24-470-CS-N** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENT TO ACCUSATION**

Respondent Abdollah Assad, M.D. . hereby files with the Nevada State Board of Pharmacy ("Board"), his Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on March 11, 2025.

ANSWER TO ACCUSATION

Jurisdiction

Dr. Assad agrees that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation. Dr. Assad further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 2-9

Paragraph 2: Dr. Assad acknowledges the factual allegations set forth in Paragraph 2.

Paragraph 3: Dr. Assad acknowledges the factual assertions set forth in Paragraph 3, however Dr. Assad asserts this was due to a misunderstanding on his part that pending matters also had to be disclosed, not only resolved matters.

Paragraph 4: Dr. Assad denies the factual allegations set forth in Paragraph 4 to the extent that he attempted to check the PMP for patient S.D. on August 18, 2024, however was unable to log into the system at that time. On September 9, 2024, Dr. Assad only prescribed seven days of Adderall due to the patient having allegedly lost some of her medication. The change in dosage was made due to the unavailability of 20 mg Adderall which the patient had been taking three times per day. Dr. Assad changed the prescription to 30 mg of Adderall twice a day; there was no modification in the daily dose of Adderall the patient was taking. Dr. Assad prescribed a fourteen day supply of Adderall on September 19, 2024.

Dr. Assad then checked the PMP to discover that the patient had been receiving controlled substances from other providers and the patient was discharged in October 2024.

Applicable Law: Paragraphs 5-11

Dr. Assad acknowledges that paragraphs 5 through 11 generally reflect the applicable laws.

Counts: Paragraphs 12-16

Paragraph 12/Count I: Dr. Assad denies the allegations contained in Paragraph 12.

Paragraph 13/Count II: Dr. Assad denies the allegations in paragraph 13.

Paragraph 14/Count III: Dr. Assad denies the allegations in paragraph 14.

Paragraph 15/Count IV: Dr. Assad denies the allegations in paragraph 15

Paragraph 16/Count V: Dr. Assad denies the allegations contained in Paragraph 16.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Dr. Assad acknowledges his failure to disclose the two Board of Medical Examiners complaints which were pending at the time he submitted his renewal and asserts the failure to

disclose the pending cases was due solely to a misunderstanding regarding disclosing pending matters, rather than matters that were resolved.

In regard to patient S.D., Dr. Assad first saw the patient on August 18, 2024. At the time the patient was currently taking Adderall as well as other medications which Dr. Assad continued the patient on. Dr. Assad does check the PMP when prescribing for any new patient, however on the day at issue, he experienced issues logging into the database.

As described above the patient was prescribed a seven day supply of Adderall on September 9, 2024, as she reported she had lost some of her pills. Dr. Assad changed the dose from 20 mg Adderall three times per day to 30 mg Adderall two times per day due to a shortage at the time of 20 mg Adderall. The daily dosage of Adderall was not altered. Dr. Assad prescribed a final fourteen day supply for the patient on September 19, 2024. Dr. Assad did check the PMP and after doing so, he discovered that the patient had been obtaining medications from other providers. Dr. Assad ultimately discharged the patient in October 2024.

Respectfully submitted this 1st day of April, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondent Abdollah Assad, M.D.

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FILED
MAR 1 1 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALYSSA GARCIA, PT,** **Certificate of Registration No. PT20499,** **Respondent.**	**CASE NO. 25-076-PT-S** **ORDER OF SUMMARY SUSPENSION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), has determined that the certificate of registration of Respondent Alyssa Garcia, PT, Certificate of Registration No. PT20499, is subject to summary suspension pursuant to Nevada Revised Statute (NRS) 233B.127(3), based upon the following preliminary findings:

1. Upon information and belief, on or about January 24, 2025, Respondent was terminated from employment by Smith's Pharmacy #315, License No. PH03897, due policy violations and unprofessional conduct related to the theft of 9,515 tablets of Alprazolam 1mg, 19,908 tablets of Alprazolam 2mg, and 1,018 tablets of Tramadol 50mg. Smith's Pharmacy #315 filed a police report with the Las Vegas Metropolitan Police Department and an investigation is ongoing.

2. As of the date of this Order, the Executive Secretary has reasonably determined that the health, safety, or welfare of the public in the State of Nevada is at risk of imminent harm based upon the finding in paragraph 1 above.

3. Based on the foregoing, the Executive Secretary has reasonably determined that a summary suspension of Certificate of Registration No. PT20499 is necessary to remove the risk of imminent harm to the health, safety and welfare of the public.

Accordingly, pursuant to NRS 233B.127(3):

IT IS HEREBY ORDERED that the Certificate of Registration No. PT20499 is **SUMMARILY SUSPENDED** until further order of the Board; and,

IT IS FURTHER ORDERED that pursuant to NRS 233B.127(3), a hearing before the Board on this matter is set for Wednesday, April 16, 2025, at 9:00 AM, or soon thereafter at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

Respondent is therefore directed to provide the Board with any evidence or information that would show that either the factual or legal reasons for the summary suspension are incorrect or otherwise demonstrate that her conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Alyssa M. Garcia
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5M

FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PULMONARY SOLUTIONS, LLC, License No. MP02951,** **Respondent.**	**CASE NO. 22-357-MP-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Pulmonary Solutions, LLC (Respondent), because Respondent holds a license issued by the Board pursuant to NRS 639.233 and NAC 639.6942.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve retail sales and/or consumer leases of medical devices, equipment, and gases.

FACTUAL ALLEGATIONS

3. Respondent is currently licensed by the Board to sell medical products from its business location at 7660 West Sahara Avenue in Las Vegas, Nevada. Respondent was previously licensed to sell medical products from a second Nevada business location at 50 Freeport Boulevard #24 in Sparks, Nevada.

4. As a licensed medical products provider, Respondent is authorized to sell and/or lease respiratory equipment and related supplies to Nevada consumers.

5. In March 2024, Respondent closed its business location at 50 Freeport Boulevard #24 in Sparks, Nevada. Respondent continues to conduct business from its location on Sahara Avenue in Las Vegas, Nevada.

6. The allegations below concern the operation of Respondent's business location in Sparks, Nevada. Until March 2024, Respondent operated the Sparks location under license no. MP02951. Respondent operates the Las Vegas location under license no. MP00687. Respondent did not renew its license for the Sparks location.

7. In August 2020, Respondent entered into a contract with patient J.E., an 88-year-old male who was suffering from chronic obstructive pulmonary disease (COPD). As directed by J.E.'s physician, Respondent supplied J.E. with a home oxygen concentrator for nocturnal use, a portable oxygen concentrator for daytime use, and associated oxygen supplies. Medicare reimbursed Respondent for the cost of the equipment and supplies.

8. Under Medicare rules, J.E. was obligated to contract with Respondent for a 5-year term of duration. Pursuant to the terms of the contract, Medicare had no obligation to pay for equipment or supplies acquired by J.E. from any source other than Respondent.

9. In 2022, as discussed in greater detail below, Respondent was largely unresponsive to J.E.'s requests for service, maintenance, and oxygen supplies. This unresponsive behavior forced J.E. to acquire oxygen supplies from Amazon at his own expense.

10. In November and December 2021, J.E.'s respiratory distress became more severe. J.E.'s physician issued an order dated December 17, 2021, directing Respondent to service J.E.'s home oxygen concentrator, to supply J.E. with an oximeter, and to provide him with a small volume nebulizer and related supplies.

11. Although Respondent received the physician's order as described above, Respondent did not service or otherwise address the problems with J.E.'s home oxygen concentrator until May 9, 2022. On that date, Respondent replaced the existing oxygen concentrator with an entirely new unit. Respondent did not document the reasons why the existing unit had failed.

12. Between December 2021 and April 2022, Respondent billed Medicare for a home oxygen concentrator and a battery that it had reportedly delivered to J.E. pursuant to his physician's

order. Respondent had not actually delivered these items to J.E. despite representing to Medicare that it had delivered the items.

13. Between December 2021 and May 9, 2022, J.E.'s various caregivers reportedly telephoned Respondent on more than 100 occasions to request service to J.E.'s home oxygen concentrator and/or to request the prescribed oximeter, the nebulizer, a battery for the portable oxygen concentrator, and much needed oxygen supplies such as masks and tubing. According to the caregivers, Respondent's employees typically complained that they were overworked, understaffed, and/or generally unable to promptly address J.E.'s medical needs.

14. Respondent did not document any of the telephone calls described above, nor did it document Respondent's responses, if any, to the calls.

15. In April 2022, Respondent dispatched a technician to examine J.E.'s home oxygen concentrator. The technician removed a piece from the home oxygen concentrator and left J.E.'s home without repairing or otherwise improving the operation or function of the home oxygen concentrator. Respondent did not make a record of this visit by the technician.

16. As noted above, on May 9, 2022, Respondent replaced J.E.'s home oxygen concentrator with an entirely new unit. Respondent's administrator has represented that Respondent's standard operating procedure is to replace rather than repair an inoperable or poorly functioning oxygen concentrator.

17. On May 10, 2022, J.E.'s caregiver telephoned Respondent to explain that J.E.'s new home oxygen concentrator was missing a part. Sometime thereafter, a technician arrived at J.E.'s home to examine the unit. According to the caregiver, the technician removed a second part from the unit and left with it. The technician never returned to repair and/or reassemble the unit. Respondent did not document the visit by the technician or the reasons why the technician had partially dissembled the unit.

18. In July and August 2022, J.E.'s caregivers telephoned Respondent on three or more occasions to inform Respondent that J.E.'s home oxygen concentrator was missing a part or parts. On

August 16, 2022, after receiving several telephone calls from J.E.'s caregivers, Respondent repaired J.E.'s home oxygen concentrator.

19. On or about November 1, 2022, Board Investigator Monica Segedy transmitted to Respondent a demand for records concerning the events described above. The demand included a request for "[a]ny and all notes documenting visits and/or communication with [J.E.] and or his caretaker." The records produced by Respondent in response to the demand letter contain very few entries documenting visits and communications with J.E. after December 2020. Respondent produced no record of ever having delivered an oximeter or a small volume nebulizer to J.E. or his caregivers as ordered by J.E.'s physician.

20. J.E. passed away on January 19, 2023.

APPLICABLE LAW

21. Any person who engages in business as a medical products provider must obtain a license from the Board. NRS 639.233; NAC 639.6942. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a consumer in Nevada.

22. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935.

23. "Respiratory equipment" means a medical product intended to assist a consumer in the act of breathing or intended to introduce a product or drug, other than a medical gas, into the lungs of a consumer. NAC 639.6938.

24. A medical products provider may be disciplined for violating, attempting to violate, assisting or abetting in the violation of federal or state statutes and regulations governing the sale, service, or maintenance of medical products. NRS 639.210(12); NRS 639.255.

25. A medical products provider may be disciplined for unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

26. Unprofessional conduct includes performing one's duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

27. Unprofessional conduct includes submitting any claim for payment or reimbursement to any person or entity for products or services that is fraudulent, deceitful, unnecessary, or for any products or services not actually provided to a consumer. NAC 639.6941(1)(f).

28. It is unprofessional conduct for a medical products provider to perform or allow any employee or agent of the medical products provider to perform services beyond the training, competency, ability or knowledge of the employee or agent. NAC 639.6941(1)(e).

29. The owner of a medical products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2).

30. A medical products provider must provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance. NAC 639.6946(1)(a).

31. A medical products provider must employ an administrator and other employees sufficient to provide set up, repair and maintenance services. NAC 639.6946(1)(b).

32. A medical products provider must communicate with its customer and/or the customer's physician when made aware of issues or problems concerning the maintenance, efficacy, or functionality of the medical products sold or leased to the customer. NAC 639.6951(2); NAC 639.6952(1)-(2). Further, the medical products provider must make a written record of all such communications. NAC 639.6951(3); NAC 639.6952(3).

33. A medical products provider that sells, leases or otherwise provides respiratory equipment must service the equipment at appropriate intervals, and keep corresponding service records, to ensure that the equipment is functional and otherwise meets the medical needs of the customer. NAC 639.6954(1)(d)-(e).

34. A medical products provider must provide an emergency supply of oxygen, supplies and equipment to maintain therapy while the primary supply of oxygen and related equipment is inoperable or unusable. NAC 639.6954(4).

35. In addition to or in lieu of revoking or suspending a person's license due to an act or omission described above, the Board may impose an administrative fine upon the person. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

COUNT ONE
Failure to Service Respiratory Equipment

36. Between December 17, 2021, and May 9, 2022, Respondent was repeatedly informed and knew that J.E.'s home oxygen concentrator required service.

37. Respondent had a legal duty to service J.E.'s home oxygen concentrator within a reasonable period of time after first being informed on or about December 17, 2021, that J.E.'s home oxygen concentrator required service. NAC 639.6946(1)(a).

38. Respondent failed to service J.E.'s home oxygen concentrator within a reasonable period of time after first being informed on or about December 17, 2021, that J.E.'s home oxygen concentrator required service.

39. Respondent failed to employ an administrator and/or other employees sufficient to service J.E.'s home oxygen concentrator within a reasonable period of time after first being informed on or about December 17, 2021, that J.E.'s home oxygen concentrator required service.

40. By failing to service J.E.'s home oxygen concentrator within a reasonable period of time, Respondent violated NAC 639.6946(1)(a).

41. By failing to employ an administrator and/or other employees sufficient to service J.E.'s home oxygen concentrator within a reasonable period of time, Respondent violated NAC 639.6946(1)(b).

42. By failing to service J.E.'s home oxygen concentrator within a reasonable period of time, and/or by failing to employ an administrator and/or other employees sufficient to service J.E.'s

home oxygen concentrator within a reasonable period of time, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

43. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT TWO
Failure to Repair Respiratory Equipment

44. On May 9, 2022, Respondent replaced J.E.'s home oxygen concentrator with an entirely new unit.

45. On or about May 10, 2022, J.E.'s caregiver telephoned Respondent to explain that J.E.'s new home oxygen concentrator was missing a part.

46. In July and August 2022, J.E.'s caregivers telephoned Respondent on three or more occasions to inform Respondent that J.E.'s home oxygen concentrator was missing a part or parts.

47. Despite receiving the several telephone calls noted above, Respondent did not repair J.E.'s home oxygen concentrator until August 16, 2022.

48. Respondent failed to repair J.E.'s home oxygen concentrator within a reasonable period of time after first being informed on or about May 10, 2022, that J.E.'s home oxygen concentrator was missing a part.

49. Respondent failed to employ an administrator and/or other employees sufficient to repair J.E.'s home oxygen concentrator within a reasonable period of time after first being informed on or about May 10, 2022, that J.E.'s home oxygen concentrator was missing a part.

50. By failing to repair J.E.'s home oxygen concentrator within a reasonable period of time, Respondent violated NAC 639.6946(1)(a).

51. By failing to employ an administrator and/or other employees sufficient to repair J.E.'s home oxygen concentrator within a reasonable period of time, Respondent violated NAC 639.6946(1)(b).

52. By failing to repair J.E.'s home oxygen concentrator within a reasonable period of time, and/or by failing to employ an administrator and/or other employees sufficient to repair J.E.'s home oxygen concentrator within a reasonable period of time, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

53. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT THREE

Failure to Communicate with a Customer Concerning Ongoing Medical Needs

54. Between December 17, 2021, and May 9, 2022, Respondent was repeatedly informed and knew that J.E.'s home oxygen concentrator required service, that he required an oximeter and nebulizer, that he required a battery for his portable oxygen concentrator, and that he required oxygen supplies such as masks and tubing.

55. Between December 17, 2021, and May 9, 2022, despite having been repeatedly informed of J.E.s immediate medical needs as described above, Respondent failed to communicate with J.E. and/or J.E.s caregivers regarding those medical needs.

56. By failing to communicate with J.E. regarding his medical needs, Respondent violated NAC 639.6951(2) and NAC 639.6952(1)-(2).

57. By failing to communicate with J.E. regarding his immediate medical needs, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

58. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT FOUR
Failure to Make a Record of Communications with a Customer

59. Between December 17, 2021, and May 9, 2022, J.E.'s caregivers repeatedly telephoned Respondent to inform Respondent that J.E.'s home oxygen concentrator required service, that he required an oximeter and nebulizer, that he required a battery for his portable oxygen concentrator, and that he required oxygen supplies such as masks and tubing. Respondent failed to make a written record of these telephone calls.

60. By failing to make a written record of telephone calls concerning J.E.'s immediate medical needs, Respondent violated NAC 639.6951(3) and NAC 639.6952(3).

61. By failing to make a written record of telephone calls concerning J.E.'s immediate medical needs, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

62. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT FIVE
Failure to Supply Emergency Oxygen and Related Supplies

63. Between December 17, 2021, and May 9, 2022, Respondent was repeatedly informed and knew that J.E.'s home oxygen concentrator required service, that he required an oximeter and nebulizer, that he required a battery for his portable oxygen concentrator, and that he required oxygen supplies such as masks and tubing. J.E.'s caregivers regularly explained that he was in urgent need of ongoing oxygen therapy.

64. Between December 17, 2021, and May 9, 2022, despite having been repeatedly informed of J.E.s urgent medical needs, Respondent failed to provide J.E. with an emergency supply of oxygen, supplies and equipment to maintain therapy while the primary supply of oxygen and related equipment was inoperable or unusable.

65. By failing to provide J.E. with an emergency supply of oxygen, supplies and equipment to maintain therapy pending repair or replacement of J.E.'s home oxygen concentrator, Respondent violated NAC 639.6954(4).

66. By failing to provide J.E. with an emergency supply of oxygen, supplies and equipment to maintain therapy pending repair or replacement of J.E.'s home oxygen concentrator, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

67. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT SIX

Failure to Service Respiratory Equipment at Appropriate Intervals

68. On or about December 17, 2021, J.E.'s physician directed Respondent to service J.E.'s home oxygen concentrator. Respondent did not properly service or otherwise address the problems with J.E.'s home oxygen concentrator until May 9, 2022.

69. On information and belief, Respondent failed to service J.E.'s home oxygen concentrator at the intervals recommended by the manufacturer.

70. By failing to service J.E.'s home oxygen concentrator at recommended intervals, Respondent violated NAC 639.6954(1)(d).

71. By failing to service J.E.'s home oxygen concentrator at recommended intervals, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

72. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT SEVEN
Failure to Make a Record of Service Call

73. In April 2022, Respondent dispatched a technician to examine J.E.'s home oxygen concentrator. The technician removed a piece from the home oxygen concentrator and left J.E.'s home without repairing or otherwise improving the operation or function of the home oxygen concentrator. Respondent did not make a record of this visit by the technician.

74. By failing to make a written record of the service call by the technician as described above, Respondent violated NAC 639.6954(1)(e).

75. By failing to make a written record of the service call by the technician as described above, Respondent performed its duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

76. Respondent is subject to professional discipline for any one or more of the acts of misconduct described above. NRS 639.210(4) and (12); NRS 639.255; NAC 639.6941(2); NAC 639.945(1)(i).

COUNT EIGHT
Failure to Employ or Engage Competent Service Technicians

77. In April 2022, Respondent dispatched a technician to examine J.E.'s home oxygen concentrator. The technician removed a piece from the home oxygen concentrator and left J.E.'s home without repairing or otherwise improving the operation or function of the home oxygen concentrator.

78. In May 2022, Respondent once again dispatched a technician to examine J.E.'s home oxygen concentrator. The technician removed a piece from the home oxygen concentrator and left J.E.'s home without repairing or otherwise improving the operation or function of the home oxygen concentrator.

79. The technician never communicated with J.E. or his caregivers regarding an anticipated repair or replacement date.

80. As evidenced by the events described above, Respondent allowed an employee or agent to perform services beyond the training, competency, ability or knowledge of the employee or agent.

Pursuant to NAC 639.6941(1)(e), this amounts to unprofessional conduct for which Respondent may be disciplined.

COUNT NINE
Improper Billing Practices

81. Between December 2021 and April 2022, Respondent billed Medicare for a home oxygen concentrator and a battery that it had reportedly delivered to J.E. pursuant to his physician's order. Respondent had not actually delivered these items to J.E. despite representing to Medicare that it had delivered the items.

82. By billing Medicare in the manner described above, Respondent submitted a claim for payment or reimbursement for products and services not actually provided to a consumer. Pursuant to NAC 639.6941(1)(f), this amounts to unprofessional conduct for which Respondent may be disciplined.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of Respondent Pulmonary Solutions, LLC.

DATED this 14th day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PULMONARY SOLUTIONS, LLC,** **License No. MP02951,** **Respondent.**	**Case No. 22-357-MP-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place Reno-Tahoe Airport
1790 E Plumb Ln.
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 1st day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PULMONARY SOLUTIONS, LLC,** **License No. MP02951,** **Respondent.**	**Case No. 22-357-MP-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR PULMONARY SOLUTIONS, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of Nov. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Pulmonary Solutions, LLC
50 Freeport Blvd., #24
Sparks, NV 89431

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

Pulmonary Solutions, LLC
22-357-MP-N
Exhibit 1

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 20th day of Nov. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Pulmonary Solutions, LLC
50 Freeport Blvd., #24
Sparks, NV 89431

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

ALERT: SEVERE WEATHER IN THE SOUTHEAST U.S AND WINTER STORMS IN THE NORTH CE...

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350314111734

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item was delivered to an individual at the address at 11:22 am on December 14, 2024 in RENO, NV 89521.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered
Delivered, Left with Individual
RENO, NV 89521
December 14, 2024, 11:22 am

Returned back to Board Office

In Transit to Next Facility
December 13, 2024

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
December 11, 2024, 6:28 pm

Arrived at USPS Regional Facility
PHOENIX AZ DISTRIBUTION CENTER
December 3, 2024, 4:21 am

Forwarded
SPARKS, NV
November 27, 2024, 7:54 am

Feedback

2218

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 20, 2024, 10:26 pm

Accepted at USPS Origin Facility
RENO, NV 89521
November 20, 2024, 9:11 pm

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

amonte Ranch Parkway Suite 206
Reno, Nevada 89521

Return Service Requested

ZIP 89521
041L12204892

MON 02 DEC 2024
WVAZ PDC 850 ZIP

Pulmonary Solutions, LLC
50 Freeport Blvd., #24
Sparks, NV 89431

-R-T-S- 894315220-1N 11/30/24

RETURN TO SENDER
UNABLE TO FORWARD
UNABLE TO FORWARD
RETURN TO SENDER

2220

le Board of Pharmacy
Ranch Parkway Suite 206
, Nevada 89521

Service Requested

9171 9690 0935 0314 1117 34

11/20/2024
US POSTAGE $011.2

Pulmonary Solutions, LLC
50 Freeport Blvd., #24
Sparks, NV 89431

PULM050 894315245-1724 12/08/24
RETURN TO SENDER
:PULMONARY SOLUTIONS
2480 N DECATUR BLVD STE 185
LAS VEGAS NV 89108-2986

RETURN TO SENDER

Pulmonary Solutions, LLC
Exhibit 2
22-357-MP-N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

March 19, 2025

Pulmonary Solutions, LLC
50 Freeport Blvd #24
Sparks, NV 89431

Re: Pulmonary Solutions, LLC and Case No. 22-357-MP-N

Dear Pulmonary Solutions, LLC,

The hearing for case number **22-357-MP-N** has been scheduled for **Wednesday, 4/16/2025** at **9:00:00 AM PST** or soon thereafter at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Jessette Phaynarikone
Administrative Assistant - Board Coordinator I
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LINCARE, INC.,** **License No. MP00015,** **Respondent.**	**Case No. 24-324-MP-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Lincare, Inc., (Respondent), because the Board has licensed Respondent to conduct business as a medical products provider.

FACTUAL ALLEGATIONS

2. Since March 9, 2001, Respondent has held license number MP00015, allowing Respondent to sell medical devices, equipment and gases at retail.

3. Respondent conducts business from a location at 3427 Goni Road #106, in Carson City, Nevada.

4. In 2019, Respondent filled patient M.O.'s prescriptions for an oxygen concentrator and a CPAP machine. Respondent delivered the oxygen concentrator to patient M.O.'s home on July 7, 2019, and the CPAP machine on November 5, 2019.

5. Respondent was charged with servicing patient M.O.'s oxygen concentrator and CPAP machine as required by Nevada law.

6. Respondent serviced patient M.O.'s oxygen concentrator on October 28, 2020, and then replaced it with a new oxygen concentrator on November 4, 2020.

7. The manufacturer of the oxygen concentrator, Philips Respironics, recommends that the machine's air inlet filter be replaced every 12 months to a maximum of 24 months or more frequently in an environment of high dust.

8. Respondent did not service patient M.O.'s oxygen concentrator or replace its air inlet filter in 2021.

9. Respondent did not service patient M.O.'s oxygen concentrator or replace its air inlet filter in 2022.

10. On March 10, 2023, patient M.O. called Respondent to request service to her oxygen concentrator. Patient M.O. explained that air was not coming out of the machine.

11. On March 31, 2023, Respondent called Respondent to advise that the only access to her home was through her garage, and to call upon arrival so that patient M.O. could let the repair person into the house through the garage.

12. Respondent did not service patient M.O.'s oxygen concentrator or replace its air inlet filter in 2023. It is unknown whether Respondent ever dispatched a repair person or technician to patient M.O.'s home in 2023. Respondent has no record of having dispatched a repair person or technician to patient M.O.'s home in 2023.

13. Patient M.O. recalls that a technician came to her home at one point in time to address a malfunction. Patient M.O. states that the technician was unable to address the problem. Respondent's records indicate that this service call likely occurred on April 7, 2024. Respondent 's records do not indicate what, if any, service or repairs were performed on April 7, 2024.

14. Respondent eventually dispatched someone to visit patient M.O.'s home on or about July 24, 2024. Respondent's record of the visit indicates that the service technician performed some type of maintenance. According to patient M.O., the service technician changed the air inlet filter but did not otherwise perform any repairs or maintenance services.

15. As explained above, Respondent did not service patient M.O.'s oxygen concentrator between November 4, 2020, and July 24, 2024, despite several calls from patient M.O. requesting service.

APPLICABLE LAW

16. Any person who engages in business as a medical products provider must obtain a license from the Board. NRS 639.233; NAC 639.6942. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a consumer in Nevada.

17. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935.

18. "Respiratory equipment" means a medical product intended to assist a consumer in the act of breathing or intended to introduce a product or drug, other than a medical gas, into the lungs of a consumer. NAC 639.6938.

19. The owner of a medical products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2).

20. A medical products provider must provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance. NAC 639.6946(1)(a).

21. A medical products provider must employ an administrator and other employees sufficient to provide set up, repair and maintenance services. NAC 639.6946(1)(b).

22. A medical products provider must communicate with its customer and/or the customer's physician when made aware of issues or problems concerning the maintenance, efficacy, or functionality of the medical products sold or leased to the customer. NAC 639.6951(2); NAC 639.6952(1)-(2). Further, the medical products provider must make a written record of all such communications. NAC 639.6951(3); NAC 639.6952(3).

23. A medical products provider that sells, leases or otherwise provides respiratory equipment must service the equipment at appropriate intervals, and keep corresponding service records, to ensure that the equipment is functional and otherwise meets the medical needs of the customer. NAC 639.6954(1)(d)-(e).

24. A medical products provider may be disciplined for violating, attempting to violate, or assisting or abetting in the violation of federal or state statutes and regulations governing the sale, service, or maintenance of medical products. NRS 639.210(12); NRS 639.255.

25. A medical products provider may be disciplined for unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.255.

26. Unprofessional conduct includes performing one's duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

27. In addition to a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Violation of NAC Chapter 639 Regulations Governing Medical Products Providers – (Respondent Lincare)

28. As alleged above, Respondent failed to service respiratory equipment furnished to patient M.O. at least every 24 months as required by the manufacturer's product manual. Failure to service such equipment according to the directions and specifications of the manufacturer is required by Nevada law. NAC 639.6954(1)(d).

29. By failing to properly service respiratory equipment furnished to patient M.O., Respondent violated NAC 639.6954(1)(d).

30. Having violated NAC 639.6954(1)(d), Respondent is subject to professional discipline. NRS 639.210(12); NRS 639.255; NAC 639.6941; NAC 639.945; and NAC 639.955.

COUNT TWO

Unprofessional Conduct - Performing Duties in an Incompetent, Unskillful, or Negligent Manner (Respondent Lincare)

31. Respondent had a duty as a licensed medical products provider to service patient M.O.'s oxygen concentrator at reasonable intervals, including those recommended by the product manufacturer. *See* NAC 639.6954(1)(d).

32. Respondent had a duty as a licensed medical products provider to exercise reasonable diligence in responding to patient M.O.'s request for service. NAC 639.6951(2); NAC 639.6952(2).

33. Respondent had a duty to communicate with patient M.O. concerning issues or problems with her oxygen concentrator. NAC 639.6951(2); NAC 639.6952(2).

34. Assuming that Respondent dispatched a repair person or service technician to patient M.O.'s home in response to her calls in 2023, Respondent had a duty to make and maintain a record of the service or maintenance performed, if any. NAC 639.6951(3); NAC 639.6952(3).

35. Respondent had a duty to employ or engage a repair person or service technician with training, competency, ability and/or knowledge sufficient to service and maintain patient M.O.'s oxygen concentrator. NAC 639.6941(1)(e).

36. Respondent failed to perform one or more of the duties specified in paragraphs 32 through 36 above, thereby performing Respondent's duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner.

37. Due to the acts and/or omissions detailed above, Respondent is guilty of unprofessional conduct for which the Board may impose professional discipline. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 11th day of JANUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LINCARE, INC.,** **License No. MP00015,** **Respondent.**	**Case No. 24-324-MP-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 17th day of JANUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LINCARE, INC.,** **License No. MP00015,** **Respondent.**	**Case No. 24-324-MP-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR LINCARE, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of January 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Lincare, Inc.
3427 Goni Rd #106
Carson City, NV 89706

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. LINCARE INC., License No. MP00015, Respondent.	CASE NO. 24-324-MP-N **OBJECTION, ANSWER, AND NOTICE OF DEFENSE**

The above-named Respondent, Lincare Inc. ("Lincare," or the "Respondent"), by and through its undersigned counsel of Holland & Hart LLP, in response to the Notice of Intended Action and Accusation (the "Accusation") filed in the above-captioned matter before the Nevada State Board of Pharmacy ("Board"), declares as follows in response to the Accusation:

OBJECTION TO ACCUSATION

Pursuant to NRS 639.244(1)(b), NRS 622A.320(1), and NRS 233B.121(4), Lincare makes the following objections to the Accusation:

1. Lincare objects to the allegations in the Accusation as incomplete and failing to fully set forth the two counts of alleged regulatory violations asserted against Lincare. The incomplete nature of these allegations include, but is not limited to, the Accusation's omission of known facts and details relating to the conduct, course of dealing, acts, and omissions of the individual identified as "patient M.O." in the Accusation ("M.O."), therefore denying Lincare the ability to fully and fairly respond to the two counts of regulatory violations alleged by the Executive Secretary of the Board (the "Secretary").

2. Lincare objects to the allegations in the Accusation as failing to clearly state allegations supporting Accusation's two counts of alleged regulatory violations. The Accusation fails to set forth claims and allegations that satisfy either of the counts alleged in the Accusation, including but not limited to the Accusation's allegations in Paragraphs 12, 13, and 14, which are unclear, ambiguous, and neither notify Lincare nor identify for the Board the facts, circumstances,

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and conduct or lack thereof, that would be counter to the regulations the Accusation alleges were violated.

ANSWER AND NOTICE OF DEFENSE

Pursuant to NRS 639.244(1)(b), NRS 622A.320(1), and NRS 233B.121(4), Lincare hereby answers each and every one of the allegations in the Accusation as follows:

JURISDICTION[1]

1. Answering Paragraph 1 of the Accusation, this paragraph contains legal conclusions to which a response is not required; nonetheless, to the extent there are factual allegations within Paragraph 1 of the Accusation that require a response, Lincare admits only that it is licensed by the Board to conduct business as a medical products provider.

FACTUAL ALLEGATIONS

2. Answering Paragraph 2 of the Accusation, Lincare admits only that at the times identified in the Accusation, it held license number MP00015; Lincare denies any and all other allegations in Paragraph 2 that are not specifically admitted within this response.

3. Answering Paragraph 3 of the Accusation, Lincare admits that it conducts business at 3427 Goni Road # 106 in Carson City, Nevada.

4. Answering Paragraph 4 of the Accusation, Lincare objects to Paragraph 4 as an improper compound allegation compiling numerous discrete and separately answerable allegations into one paragraph. Notwithstanding the foregoing objection and without waiving the same, Lincare admits only that in 2019 it filled M.O.'s prescriptions for an oxygen concentrator and CPAP machine; further admits that Lincare delivered the oxygen concentrator and CPAP machine to Respondent on July 7, 2019 and November 5, 2019, respectively; and Lincare further avers that M.O. signed for and accepted delivery of both devices on the dates set forth above. All allegations within Paragraph 4 of the Accusation not specifically admitted herein are denied.

[1] The headings used by Lincare in this Objection, Answer and Notice of Defense in response to the Accusation are copied from the Accusation for organizational purposes only; Lincare's adoption of these headings does not constitute and cannot be construed as any admission as to any fact.

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5. Answering Paragraph 5 of the Accusation, this paragraph contains legal conclusions to which a response is not required; nonetheless, to the extent there are factual allegations within Paragraph 5 of the Accusation that require a response, Lincare denies them. Lincare further disputes the allegations within Paragraph 5 on the basis that M.O.'s actions or absence thereof excused, terminated, limited, or otherwise negated Lincare's "charge[]" alleged to exist within Paragraph 5.

6. Answering Paragraph 6 of the Accusation, Lincare admits the allegations therein.

7. Answering Paragraph 7 of the Accusation, this paragraph contains allegations regarding the recommendations of a third party during an unspecified time period, and further relates to documents, policies, and procedures, the contents of which speak for themselves. Accordingly, no response to Paragraph 7's allegations is required; to the extent there are factual allegations within Paragraph 7 of the Accusation that require a response, Lincare denies Paragraph 7's allegations for lack of firsthand knowledge.

8. Answering Paragraph 8 of the Accusation, Lincare denies the allegations within Paragraph 8, and further alleges that its efforts to provide the service at issue in Paragraph 8 to M.O. were frustrated or denied for circumstances beyond its control, including but not limited to the COVID-19 pandemic ("Pandemic"), restrictions on Lincare's operations during the Pandemic, the consequences of the Pandemic and its various state and federal orders affecting the availability of care in patients' homes, considerations regarding M.O.'s underlying respiratory conditions during the Pandemic, and M.O.'s actions or absence thereof in connection with Lincare's attempts to provide the services described in Paragraph 8 of the Accusation.

9. Answering Paragraph 9 of the Accusation, Lincare denies the allegations within Paragraph 9, and further alleges that its efforts to provide the service at issue in Paragraph 9 to M.O. were frustrated or denied for circumstances beyond its control, including but not limited to the Pandemic, restrictions on Lincare's operations during the Pandemic, the consequences of the Pandemic and its various state and federal orders affecting the availability of care in patients' homes, considerations regarding M.O.'s underlying respiratory conditions during the Pandemic,

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and M.O.'s actions or absence thereof in connection with Lincare's attempts to provide the services described in Paragraph 9 of the Accusation.

10. Answering Paragraph 10 of the Accusation, Lincare admits only that on March 10, 2023, M.O. called Lincare to request service to her oxygen concentrator; Lincare denies any and all other allegations in Paragraph 10 that are not specifically admitted within this response.

11. Answering Paragraph 11 of the Accusation, Lincare objects to this paragraph's allegations as ambiguous and unintelligible, as it alleges "Respondent called Respondent [sic]" as the basis for its contentions. Lincare is not required to guess the meaning of this Paragraph's allegations. Based on these objections and without waiving the same, to the extent it is compelled to respond to the contents of Paragraph 11's allegations as stated, Lincare denies them.

12. Answering Paragraph 12 of the Accusation, Lincare objects to Paragraph 12 as an improper compound allegation compiling numerous discrete and separately answerable allegations into one paragraph. Notwithstanding the foregoing objection and without waiving the same, admits only that it did not service M.O.'s oxygen concentrator or replace its air inlet filter in 2023, denies all allegations within Paragraph 12 not expressly admitted herein, and further avers that Lincare did, in fact, dispatch a repair person or technician to M.O.'s home in 2023, and that M.O. denied access to and/or refused service from Lincare's representative at this time.

13. Answering Paragraph 13 of the Accusation, Lincare objects to this paragraph's allegations as vague, ambiguous, unclear, and therefore difficult to fairly answer, specifically as the Paragraph relates to "a malfunction" but does not identify which device was checked for a malfunction. Lincare also objects to Paragraph 13 as an improper compound allegation compiling numerous discrete and separately answerable allegations into one paragraph. Notwithstanding the foregoing objections and without waiving the same, Lincare denies the allegations within Paragraph 13 of the Accusation. Lincare further avers that it dispatched a repair person or technician to M.O.'s residence on April 7, 2023, rather than April 7, 2024, as alleged in the Accusation, and that M.O. sent away Lincare's representative prior to performing maintenance

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or repairs on M.O.'s device(s), rather than Lincare's representative being "unable to address the problem" due to lack of knowledge, skill, or ability.

14. Answering Paragraph 14 of the Accusation, Lincare admits only that a representative visited M.O.'s house on July 24, 2024 and performed a maintenance check on M.O.'s oxygen concentrator; Lincare denies all remaining allegations within Paragraph 14 of the Allegation not specifically admitted herein.

15. Answering Paragraph 15 of the Accusation, Lincare denies the allegations within Paragraph 15. Lincare further objects to this Paragraph's allegations as misstatements of fact, to the extent Paragraph 15 misstates and is contradicted by both the Accusation's allegations and Lincare's averrals set forth herein.

APPLICABLE LAW

16. Answering Paragraphs 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, and 27 of the Accusation, these paragraphs contain legal conclusions to which response are not required; however, to the extent these paragraphs contain or could be construed to contain any factual allegations to which responses in the form of admissions or denials are required, Lincare denies each and every allegation within Paragraphs 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, and 27, inclusive.

COUNT ONE

17. Answering Paragraph 28 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 28.

18. Answering Paragraph 29 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 29.

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19. Answering Paragraph 30 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 30.

COUNT TWO

20. Answering Paragraph 31 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 31.

21. Answering Paragraph 32 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 32.

22. Answering Paragraph 33 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 33. Lincare further avers that it duly discharged and satisfied any legal obligation it may have had to communicate with M.O., and any lack of communication was the result of M.O.'s conduct or inaction.

23. Answering Paragraph 34 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 34.

24. Answering Paragraph 35 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 35.

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25. Answering Paragraph 36 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 36.

26. Answering Paragraph 37 of the Accusation, this paragraph contains legal conclusions to which a response is not required; however, to the extent this paragraph contains any factual allegations to which a response is required, Lincare denies the allegations within Paragraph 37.

AFFIRMATIVE DEFENSES

Lincare asserts and raises the following affirmative defenses to the Board's allegations contained within the Accusation:

1. The Accusation, in whole or in part, fails to state a claim upon which relief may be granted.

2. M.O.'s conduct or inaction, including through telephonic communication or lack thereof, and interactions with Lincare representatives, are the proximate cause of the regulatory violations alleged in the Accusation.

3. M.O.'s conduct or inaction, including through telephonic communication or lack thereof, and interactions with Lincare representatives, are a superseding or intervening cause for the regulatory violations alleged in the Accusation.

4. Federal and state governmental actions, emergency orders, emergency regulations, guidance, and other directives during the Pandemic (the "Pandemic Orders"), were intervening and/or superseding and affected the availability and manner of Lincare's services, including as they related to home-based maintenance requests by M.O. as it related to equipment for M.O.'s oxygenation and underlying respiratory condition.

5. Lincare's activities described in the Accusation are excused, justified, and/or privileged or immunized against any liability based on the Pandemic Orders.

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LAS VEGAS, NV 89134

6. At all times, Lincare took all reasonable actions available to comply with manufacturer requirements for the maintenance of M.O.'s devices, to the extent permitted by M.O.'s conduct and the effects of Pandemic Orders, as well as the Pandemic generally.

7. Lincare exercised due care and good faith towards M.O. in performing its duties and/or made a good faith effort to comply with all applicable statutes and regulations.

8. The Board has not alleged any facts to demonstrate any harm or damages, whether public or private, resulting from Lincare's alleged acts or omissions.

9. The Board's claims are barred by the doctrines of laches and estoppel.

10. The Board's claims are barred in equity and based on M.O.'s conduct as described in Lincare's averrals herein and may be proven at a hearing on the above-captioned matter.

11. All possible affirmative defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of Lincare's Answer and Notice of Defense, and insofar as the Accusation is couched in compound, ambiguous, vague, confusing, and conclusory terms. Lincare therefore reserves the right to amend this Answer and Notice of Defense, and assert additional affirmative defenses as may be supported by the facts and evidence adduced prior to hearing.

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HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

PRAYER FOR RELIEF

WHEREFORE, Lincare respectfully requests the following relief be granted by the Board:

1. That following the hearing this action be dismissed with prejudice;

2. That the Board award Lincare's attorneys' fees and costs incurred in defense of this action; and

3. For such other and further relief as the Board deems proper.

DATED this 24th day of February 2025.

J. Malcolm DeVoy, Esq.
Sydney R. Gambee, Esq.
HOLLAND & HART LLP
9555 Hillwood Drive, Second Floor
Las Vegas, Nevada 89134
Telephone: 702-669-4636
jmdevoy@hollandhart.com
srgambee@hollandhart.com

Attorneys for Respondent

CERTIFICATE OF SERVICE

I, the employee of Holland & Hart LLP identified below, certify that on this 24th day of February, 2025, I served two (2) copies of the foregoing **OBJECTION, ANSWER, AND NOTICE OF DEFENSE** in Case No. 24-324-MP-N to the Nevada State Board of Pharmacy via U.S. Mail to the address set forth below, and by emailing a copy of this document to the Board of Pharmacy's coordinating staff at the email addresses below:

Gregory Zunino
Senior General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521
TeamBC@Pharmacy.nv.gov.
zunino@pharmacy.nv.gov

An Employee of Holland & Hart LLP

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HOLLAND & HART LLP
9555 HILLWOOD DRIVE, 2ND FLOOR
LAS VEGAS, NV 89134

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FILED
JAN 30 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, P.A.,** **Certificate of Registration No. PR14531,** **Respondent.**	**CASE NO. 20-070-PR-N** **ORDER TO SHOW CAUSE**

1. On April 17, 2024, the Nevada State Board of Pharmacy (Board) disciplined Respondent Heliodoro Magana (Respondent) for prescribing controlled substances without legal authority in violation of NRS 639.100. Respondent's unprofessional conduct and/or violations of Nevada law are more particularly described in the Board's Findings of Fact, Conclusions of Law and Order dated April 17, 2024 (Order).

2. For the unprofessional conduct and/or violations of Nevada law as described in the Order, the Board revoked Respondent's Certificate of Registration No. PR14531. Additionally, the Board directed Respondent to pay an administrative fine of $10,000, and to partially reimburse the Board for its recoverable costs of investigation and prosecution in the amount of $544.55.

3. As of January 21, 2025, Respondent had not paid the fine or fees imposed via the Board's Order.

4. Should Respondent choose to petition the Board to reinstate his privilege to prescribe prescription drugs in Nevada, he must demonstrate that he has the character and fitness to hold a certificate of registration to prescribe prescription drugs.

5. Having failed to comply with the Board's Order, Respondent has demonstrated that he may lack the character and fitness to hold a certificate of registration to prescribe prescription drugs.

6. To memorialize Respondent's noncompliance with the Board's Order, the Board intends to issue a public reprimand and/or impose additional discipline not inconsistent with the provisions of chapter 639 of NRS.

7. Pursuant to NAC 639.960, a record of such discipline, if imposed, shall be forwarded to the National Practitioner Data Bank, where it will put licensing authorities, insurers, and/or employers on public notice of Respondent's noncompliance with the Order.

8. Accordingly, pursuant to NAC 639.965, Respondent shall appear before the Board at the next regularly scheduled meeting to show cause why he should not be publicly reprimanded and/or disciplined for having failed to comply with the terms of the Order.

NOW, THEREFORE, IT IS HEREBY ORDERED that Respondent Heliodoro Magana appear before the Board and show cause, if any, why he should not be publicly reprimanded and/or disciplined for having failed to comply with the Order.

DATED this 30th day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to dispute the allegations of noncompliance as set forth above. NRS 233B.127(3); NAC 639.968.

The Board has scheduled your hearing on this matter for Wednesday, April 16, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 E Plumb Lane, Reno, Nevada. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3RD day of FEBRUARY 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Heliodoro Magana, P.A.
c/o Lags Spine and Sportscare Medical Center
3967 S McCarran Blvd
Reno, NV 89502

Eleanor D. Murphy, Esq.
7900 W Sahara Ave., Ste. 200
Las Vegas, NV 89117

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
APR 17 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, PA,** **Certificate of Registration No. PR14531,** **Respondent.**	**Case No. 20-070-PR-N** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, April 17, 2024. Gustaf Vanderdonck, Esq., prosecuted the case before the Board. Respondent Heliodoro Magana, P.A., Certificate of Registration No. PR14531, failed to appear. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Heliodoro Magana, P.A. (Respondent), because the at the time of the violations alleged herein, Respondent held a certificate of registration issued by the Board pursuant to NRS 639.1373, authorizing Respondent to write prescriptions for dangerous drugs as a Physician's Assistant. Since March 18, 2019, Respondent has held certificate of registration no. PR14531, allowing Respondent to prescribe dangerous drugs.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070

3. Respondent is a Physician's Assistant who practiced at Lags Spine & SportsCare Medical Centers, located at 3967 S. McCarran Blvd., Reno, NV 89502, at the time of the events alleged herein.

4. Respondent has been registered by the Board to prescribe dangerous drugs pursuant to NRS 639.1373 since March 18, 2019.

5. Respondent has never held a controlled substance certificate of registration with the Board.

6. In Nevada, prior to prescribing controlled substances, a Physician's Assistant must obtain a controlled substance certificate of registration with the Board pursuant to NRS 453.226.

7. A requirement of possessing a controlled substance registration with the Board and prescribing controlled substances in Nevada is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

8. Respondent never had a Nevada PMP account.

9. Board PMP Compliance Coordinator Dave Jones conducts audits of practitioners to ensure that they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

10. Board PMP Compliance Coordinator Jones attempted to conduct an audit of Respondent's PMP account.

11. Board PMP Compliance Coordinator Jones found that Respondent was never issued a Nevada controlled substance certificate of registration. Respondent also never was able to establish a Nevada PMP account.

12. Respondent was never able to review the prescriptions for controlled substances he had written every six (6) months, as required by NRS 453.164(7).

13. Additionally, Respondent was not able to individually query any patient he prescribed controlled substances to for the first time, or every ninety (90) days thereafter, if applicable, as required by NRS 639.23507.

14. Respondent wrote at least 690 total prescriptions for controlled substances between the dates of March 18, 2018, and January 12, 2022.

15. Respondent wrote prescriptions for at least 150 unique patients during this time period.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

16. The Board has jurisdiction over this matter and this Respondent, because at the time of the events herein, Respondent held a Prescriber certificate of registration issued by the Board.

17. Respondent failed to file a Notice of Defense to the Accusation, which constituted a waiver of the Respondent's right to a hearing. NRS 639.244(2).

18. Board staff satisfied the notice and service requirements of NRS 233B.127(3), NRS 639.242, and NRS 639.245, and Respondent was given sufficient legal notice of the hearing.

19. The applicable law in this matter is as follows:

A. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions

issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

B. Every practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State shall obtain a certificate of registration with the Board. NRS 453.226(1).

C. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

D. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

E. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

F. Unprofessional conduct includes, "performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration." NAC 639.945(1)(k).

G. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

20. Having failed to appear at the April 17, 2024, hearing, and pursuant to NRS 622A.350(1) and (2), the Board accepts the allegations of fact and alleged violations of law contained in the Accusation against Respondent as true, and hereby finds Respondent guilty of the following:

A. Respondent Magana Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i). Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law. See NRS 453.164(7) and NAC 639.945(1)(i). Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945

B. Respondent Magana engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i). Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on any patients Respondent prescribed controlled substances to between March 18, 2018, and January 12, 2022. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945

C. Respondent Magana engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration. NRS 453.226(1) and NAC 639.945(1)(k). Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration because Respondent prescribed controlled substances in Nevada without having obtained a Nevada controlled substance certificate of registration. See NRS 453.226(1) and NAC 639.945(1)(k). A Nevada controlled substance certificate of registration is required to prescribe controlled substances in Nevada. NRS 453.226(1). 34.

Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

21. Respondent's Certificate of Registration No. PR14531 is hereby **REVOKED** pursuant to NRS 639.210 and/or NRS 639.255.

22. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition the Board for reinstatement for a period of **one (1) year.**

23. Respondent has **no authority to prescribe drugs in the state of Nevada** or to Nevada based patients in any capacity unless and until they have petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates their certificate of registration. (This section does not apply if a Nevada based patient visits the Respondent in a different state where the Respondent holds a valid registration to prescribe drugs and Respondent prescribes that drug for the Nevada based patient in a legal manner).

24. In the event Respondent applies for any registration or certificate with the Board, he **shall appear before the Board** to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

25. Respondent shall pay **Ten Thousand Dollars and Zero Cents ($10,000.00)** for the alleged violations, payable by *cashier's check or certified check or money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

26. Respondent shall pay **Five Hundred and Forty Four Dollars and Fifty-Five Cents ($544.55)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check or certified check or money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

27. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 453 and Chapter 639.

28. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

29. This Order will be reported to federal and/or state authorities as consistent with federal and/or state laws and regulations.

30. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17th day of April, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Heliodoro Magana, PA
[redacted]
Reno, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

FILED
FEB 28 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, PA,** **Certificate of Registration No. PR14531,** **Respondent.**	**Case No. 20-070-PR-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Heliodoro Magana, P.A. (Respondent), because the at the time of the violations alleged herein, Respondent held a certificate of registration issued by the Board pursuant to NRS 639.1373, authorizing Respondent to write prescriptions for dangerous drugs as a Physician's Assistant. Since March 18, 2019, Respondent has held certificate of registration no. PR14531, allowing Respondent to prescribe dangerous drugs.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent is a Physician's Assistant who practiced at Lags Spine & SportsCare Medical Centers, located at 3967 S. McCarran Blvd., Reno, NV 89502, at the time of the events alleged herein.

4. Respondent has been registered by the Board to prescribe dangerous drugs pursuant to NRS 639.1373 since March 18, 2019.

5. Respondent has never held a controlled substance certificate of registration with the Board.

6. In Nevada, prior to prescribing controlled substances, a Physician's Assistant must obtain a controlled substance certificate of registration with the Board pursuant to NRS 453.226.

7. A requirement of possessing a controlled substance registration with the Board and prescribing controlled substances in Nevada is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

8. Respondent never had a Nevada PMP account.

9. Board PMP Compliance Coordinator Dave Jones conducts audits of practitioners to ensure that they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

10. Board PMP Compliance Coordinator Jones attempted to conduct an audit of Respondent's PMP account.

11. Board PMP Compliance Coordinator Jones found that Respondent was never issued a Nevada controlled substance certificate of registration. Respondent also never was able to establish a Nevada PMP account.

12. Respondent was never able to review the prescriptions for controlled substances he had written every six (6) months, as required by NRS 453.164(7).

13. Additionally, Respondent was not able to individually query any patient he prescribed controlled substances to for the first time, or every ninety (90) days thereafter, if applicable, as required by NRS 639.23507.

14. Respondent wrote at least 690 total prescriptions for controlled substances between the dates of March 18, 2018, and January 12, 2022.

15. Respondent wrote prescriptions for at least 150 unique patients during this time period.

APPLICABLE LAW

16. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

17. Every practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State shall obtain a certificate of registration with the Board. NRS 453.226(I).

18. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

19. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

20. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

21. Unprofessional conduct includes, "performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration." NAC 639.945(1)(k).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Query PMP Every 6 Months

23. Respondent never established his PMP account. Since Respondent never had an active PMP account between the dates of March 18, 2018, and January 12, 2022, Respondent was never able to review his PMP account every six (6) months to ensure that the information in the account concerning the practitioner, including the legitimacy or validity of the prescriptions Respondent is shown as having written was correct. *See* NRS 453.164(7). During this period, Respondent wrote over 690 prescriptions for controlled substances.

24. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

25. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law. *See* NRS 453.164(7) and NAC 639.945(1)(i). The information regarding the practitioner that Respondent was and still is required to look at includes information concerning the prescriptions written by the practitioner. *See* NRS 453.164(7). A check of the PMP account at least once every six (6) months ensures that a practitioner has not had their credentials stolen or duplicated and that, if they have been stolen or duplicated, the Board is notified of any potentially forged prescriptions by the practitioner in a timely manner. *See* NRS 453.164(7). The required six (6) month check of a practitioner's PMP account guards against forged controlled substance prescriptions and allows practitioners to work with the Board to stop them in real time. *See* NRS 453.164(7).

26. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

COUNT TWO

Unprofessional Conduct – Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance

27. Between March 18, 2018, and January 12, 2022, Respondent was never able to conduct an individual PMP patient inquiry because Respondent had not established an account. During the same period, Respondent wrote over 690 prescriptions for over 150 unique patients.

28. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

29. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on any patients Respondent prescribed controlled substances to during the time period referenced in paragraph 27. *See* NRS 639.23507 and NAC 639.945(1)(i).

30. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

COUNT THREE

Unprofessional Conduct – Prescribing Controlled Substances in Nevada Without Having the Authority to do so

31. Respondent never possessed a Nevada controlled substance certificate of registration. Respondent wrote over 690 prescriptions for controlled substances in Nevada without possessing the required certificate of registration to do so.

32. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration. NRS 453.226(1) and NAC 639.945(1)(k).

33. Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration because Respondent prescribed controlled substances in Nevada without having obtained a Nevada controlled substance certificate of registration. *See* NRS 453.226(1) and NAC 639.945(1)(k). A Nevada controlled substance certificate of registration is required to prescribe controlled substances in Nevada. NRS 453.226(1).

34. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, PA** **Certificate Of Registration No. PR14531,** **Respondent.**	**Case No. 20-070-PR-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 27th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, PA,** **Certificate of Registration No. PR14531,** **Respondent.**	**Case No. 20-070-PR-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

HELIODORO MAGANA, PA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of February 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Heliodoro Magana, PA
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

John H. Cotton, Esq.
Nevada Bar Number 5268
JHCotton@jhcottonlaw.com
Brad J. Shipley, Esq.
Nevada Bar Number 12639
BShipley@jhcottonlaw.com
JOHN H. COTTON & ASSOCIATES, LTD.
7900 West Sahara Avenue, Suite 200
Las Vegas, Nevada 89117
Telephone: (702) 832-5909
Facsimile: (702) 832-5910
Attorneys for Respondents

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. HEILOODORO MAGANA, P.A., Respondent.	CASE NOS.: **20-070-PR-N** **PETITION TO SET ASIDE OR VACATE APRIL 17, 2024 FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER, AND RESPONSE TO ORDER TO SHOW CAUSE**

Respondent, HELIODORO MAGANA, P.A., (hereinafter "Respondent"), by and through their counsel of record, John H. Cotton, Esq. and Brad J. Shipley, Esq., of the law firm of JOHN H. COTTON & ASSOCIATES, LTD., hereby petitions to set aside or vacate the April 17, 2024 Findings of Fact, Conclusions of Law, and Order, and responds to the order to show cause issued against him based on all the papers, pleadings, documents on file, and all applicable statutes and case law, and the following memorandum of points and authorities:

Dated this 2nd day of April 2025.

/s/ Brad J. Shipley
John H. Cotton, Esq.
Brad J. Shipley, Esq.
JOHN H. COTTON & ASSOCIATES, LTD.
7900 West Sahara Avenue, Suite 200
Las Vegas, Nevada 89117
Attorneys for Respondents

John H. Cotton & Associates
7900 W. Sahara, Suite 200
Las Vegas, NV 89117

Memorandum of Points and Authorities

I. Introduction

Good cause exists to set aside the Nevada State Board of Pharmacy's ("the Board") findings of fact, conclusions of law, and order that were issued on April 17, 2024. Nevada law has long-recognized a strong policy preference for decisions on the merits and this case is no different. Through no fault of his own, respondent Heliodoro "Hector" Magana, PA, was never served with any complaint from the Board and therefore failed to respond or otherwise defend against the allegations. A finding was issued against him without any actual notice to him and therefore no opportunity to be heard.

Respondent therefore respectfully requests that the findings of fact, conclusions of law, and order that were issued on April 17, 2024, be set aside or vacated, and that he be given the opportunity to present a defense to the allegations in this matter.

II. Relevant Facts

On April 17, 2024, the Board issued a findings of fact, conclusions of law, and order ("FFCL"). **Exhibit A, FFCL**. The FFCL acknowledges that it was issued based upon a failure of the Respondent to "file a Notice of Defense to the Accusation, which constituted a waiver of Respondent's right to a hearing." *Id*. at 3. Nowhere in the FFCL is there any finding that the respondent had *actual* notice of the hearing, instead relying upon service through certified mail to the respondent's last known address as allowed by statute. The FFCL issued a harsh punishment against Respondent, revoking his Certificate of Registration, imposing a $10,000 fine and also costs of $544.55. *Id* at 7.

Respondent never received any notice of the Board's April 2024 hearing or FFCL until he happened to perform an internet search of his own name in July 2024. **Exhibit B**, **Declaration of Heliodoro Magana, PA**. Respondent promptly retained counsel to attempt to address the FFCL at that time. Unfortunately, former counsel did not promptly file a motion to set aside the FFCL before leaving the employment of the firm. **Exhibit C**, **Declaration of Counsel**.

At this time, Respondent is admittedly not in compliance with the Board's FFCL, and the case is set for an order to show cause on April 16, 2025. Respondent has acknowledged notice of

that hearing and fully intends to appear at that time with counsel. **Exhibit B**.

III. Argument

Both the Fifth and Fourteenth Amendments of the United States Constitution provide for procedural due process before one can be deprived of "life, liberty, *or property*..." (emphasis added). The notion of due process is at least as old as Clause 39 of the Magna Carta and has been a well-established right going on eight centuries. The United States Supreme Court has itself addressed the limits of these due process protections. In *Goldberg v. Kelly*, 397 US 254 (1970), the Supreme Court found that due process requires, at minimum, notice and opportunity to be heard.

Nevada law also has a longstanding, strong policy preference for decisions on the merits. *See e.g.*, *Price v. Dunn,* 106 Nev. 100 (1990), *Hansen v. Universal Health Services, Inc.*, 112 Nev. 1245, 1248 (1996), and *Huckabay Props v. NC Auto Parts, LLC,* 130 Nev. 196 (2014).

Respondent understands that Nevada law allows for service by certified mail for administrative actions, however, at the time that service was made in this case, Respondent was not actively practicing in Nevada and was also no longer receiving mail at his address of record. He did not receive any actual notice of this case, and the failure to respond was the result of that lack of notice.

Given that Respondent had no notice of the hearing, the FFCL cannot be said to satisfy basic due process protections. Respondent therefore moves to have the FFCL set aside or vacated, and to allow for an opportunity for a decision on the merits consistent with Nevada's longstanding policy preference for the same.

Respondent furthermore submits that his lack of knowledge of the existence of the case is good cause for having so far failed to comply with the terms of the order. Respondent respectfully submits that should the Board deny his request to set aside or vacate the FFCL, there is nonetheless good cause for the Board not to impose any additional discipline or penalties.

IV. Conclusion

Based on the foregoing, Respondent respectfully requests that the April 17, 2024 Findings of Fact, Conclusions of Law and Order be set aside or vacated and that Respondent be

John H. Cotton & Associates
7900 W. Sahara, Suite 200
Las Vegas, NV 89117

permitted an opportunity to address the allegations on the merits.

Dated this 2nd day of April 2025.

/s/ Brad J. Shipley
John H. Cotton, Esq.
Brad J. Shipley, Esq.
JOHN H. COTTON & ASSOCIATES, LTD.
7900 West Sahara Avenue, Suite 200
Las Vegas, Nevada 89117
Attorneys for Respondents

John H. Cotton & Associates
7900 W. Sahara, Suite 200
Las Vegas, NV 89117

CERTIFICATE OF SERVICE

I hereby certify that on the 2nd day of April 2025, I served a true and correct copy of the foregoing **PETITION TO SET ASIDE OR VACATE APRIL 17, 2024 FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER, AND RESPONSE TO ORDER TO SHOW CAUSE** was served on the following via email:

Gregory Zunino
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, Nevada 89521
Phone: (775) 850-1440
Fax: (775) 850-1444
zunino@pharmacy.nv.gov

/s/ Flor Gonzalez-Pacheco
An Employee of John H. Cotton & Associates, Ltd.

John H. Cotton & Associates
7900 W. Sahara, Suite 200
Las Vegas, NV 89117

EXHIBIT A

EXHIBIT A

FILED
APR 17 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HELIODORO MAGANA, PA,** **Certificate of Registration No. PR14531,** **Respondent.**	**Case No. 20-070-PR-N** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, April 17, 2024. Gustaf Vanderdonck, Esq., prosecuted the case before the Board. Respondent Heliodoro Magana, P.A., Certificate of Registration No. PR14531, failed to appear. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Heliodoro Magana, P.A. (Respondent), because the at the time of the violations alleged herein, Respondent held a certificate of registration issued by the Board pursuant to NRS 639.1373, authorizing Respondent to write prescriptions for dangerous drugs as a Physician's Assistant. Since March 18, 2019, Respondent has held certificate of registration no. PR14531, allowing Respondent to prescribe dangerous drugs.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070

3. Respondent is a Physician's Assistant who practiced at Lags Spine & SportsCare Medical Centers, located at 3967 S. McCarran Blvd., Reno, NV 89502, at the time of the events alleged herein.

4. Respondent has been registered by the Board to prescribe dangerous drugs pursuant to NRS 639.1373 since March 18, 2019.

5. Respondent has never held a controlled substance certificate of registration with the Board.

6. In Nevada, prior to prescribing controlled substances, a Physician's Assistant must obtain a controlled substance certificate of registration with the Board pursuant to NRS 453.226.

7. A requirement of possessing a controlled substance registration with the Board and prescribing controlled substances in Nevada is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

8. Respondent never had a Nevada PMP account.

9. Board PMP Compliance Coordinator Dave Jones conducts audits of practitioners to ensure that they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

10. Board PMP Compliance Coordinator Jones attempted to conduct an audit of Respondent's PMP account.

11. Board PMP Compliance Coordinator Jones found that Respondent was never issued a Nevada controlled substance certificate of registration. Respondent also never was able to establish a Nevada PMP account.

12. Respondent was never able to review the prescriptions for controlled substances he had written every six (6) months, as required by NRS 453.164(7).

13. Additionally, Respondent was not able to individually query any patient he prescribed controlled substances to for the first time, or every ninety (90) days thereafter, if applicable, as required by NRS 639.23507.

14. Respondent wrote at least 690 total prescriptions for controlled substances between the dates of March 18, 2018, and January 12, 2022.

15. Respondent wrote prescriptions for at least 150 unique patients during this time period.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

16. The Board has jurisdiction over this matter and this Respondent, because at the time of the events herein, Respondent held a Prescriber certificate of registration issued by the Board.

17. Respondent failed to file a Notice of Defense to the Accusation, which constituted a waiver of the Respondent's right to a hearing. NRS 639.244(2).

18. Board staff satisfied the notice and service requirements of NRS 233B.127(3), NRS 639.242, and NRS 639.245, and Respondent was given sufficient legal notice of the hearing.

19. The applicable law in this matter is as follows:

A. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions

issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

B. Every practitioner or other person who dispenses any controlled substance within this State or who proposes to engage in the dispensing of any controlled substance within this State shall obtain a certificate of registration with the Board. NRS 453.226(1).

C. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

D. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

E. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

F. Unprofessional conduct includes, "performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration." NAC 639.945(1)(k).

G. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

20. Having failed to appear at the April 17, 2024, hearing, and pursuant to NRS 622A.350(1) and (2), the Board accepts the allegations of fact and alleged violations of law contained in the Accusation against Respondent as true, and hereby finds Respondent guilty of the following:

A. Respondent Magana Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i). Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law. See NRS 453.164(7) and NAC 639.945(1)(i). Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945

B. Respondent Magana engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i). Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on any patients Respondent prescribed controlled substances to between March 18, 2018, and January 12, 2022. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945

C. Respondent Magana engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration. NRS 453.226(1) and NAC 639.945(1)(k). Respondent performed an act for which obtaining a certificate of registration was required without having obtained the required certificate of registration because Respondent prescribed controlled substances in Nevada without having obtained a Nevada controlled substance certificate of registration. See NRS 453.226(1) and NAC 639.945(1)(k). A Nevada controlled substance certificate of registration is required to prescribe controlled substances in Nevada. NRS 453.226(1). 34.

Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

21. Respondent's Certificate of Registration No. PR14531 is hereby **REVOKED** pursuant to NRS 639.210 and/or NRS 639.255.

22. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition the Board for reinstatement for a period of **one (1) year.**

23. Respondent has **no authority to prescribe drugs in the state of Nevada** or to Nevada based patients in any capacity unless and until they have petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates their certificate of registration. (This section does not apply if a Nevada based patient visits the Respondent in a different state where the Respondent holds a valid registration to prescribe drugs and Respondent prescribes that drug for the Nevada based patient in a legal manner).

24. In the event Respondent applies for any registration or certificate with the Board, he **shall appear before the Board** to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

25. Respondent shall pay **Ten Thousand Dollars and Zero Cents ($10,000.00)** for the alleged violations, payable by *cashier's check or certified check or money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

26. Respondent shall pay **Five Hundred and Forty Four Dollars and Fifty-Five Cents ($544.55)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check or certified check or money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order.

27. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 453 and Chapter 639.

28. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

29. This Order will be reported to federal and/or state authorities as consistent with federal and/or state laws and regulations.

30. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17th day of April, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Heliodoro Magana, PA
3967 S McCarran Blvd
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

EXHIBIT B

EXHIBIT B

DECLARATION OF HELIODORO MAGANA, PA

STATE OF NEVADA)
) : ss.
COUNTY OF WASHOE)

HELIODORO MAGANA being duly sworn, deposes and states:

1. Declarant is a resident of Sacramento County, California, over the age of 18, and competent to make this declaration.

2. Declarant is a Physician Assistant, currently practicing in the State of California. Declarant is not currently practicing in the state of Nevada and has not for several years.

3. Declarant is currently aware of case 20-70-PR-N before the Nevada State Board of Pharmacy. Declarant was not, however, aware of that case until July of 2024.

4. At that time, declarant became aware of the case when he performed a google search of his own name.

5. Declarant was never personally served with any complaint from the Nevada State Board of Pharmacy nor did he ever receive any emails related to the same.

6. Declarant did not have any actual knowledge of the case until *after* a default was already entered against him in hearing where he was not present in April of 2024.

7. Upon learning of the case, declarant promptly sought counsel to attempt to defend himself before the Nevada State Board of Pharmacy.

8. Declarant would like an opportunity to defend himself against any and all allegations made against him by the Nevada State Board of Pharmacy.

9. Declarant furthermore submits that his failure to participate in the process previously was the result of excusable neglect as he lacked any actual knowledge of the proceedings.

10. Declarant is competent to testify as to the matters contained herein and furthermore acknowledges notice of the hearing on April 16, 2025, in Reno, Nevada, and intends to appear at

that hearing with counsel.

11. This declaration is made subject to the laws of penalty of perjury of the State of Nevada and the State of California.

Further the declarant sayeth naught.

HELIODORO MAGAN, PA

EXHIBIT C

EXHIBIT C

DECLARATION OF BRAD J. SHIPLEY, ESQ.

STATE OF NEVADA)
) : ss.
COUNTY OF CLARK)

BRAD J. SHIPLEY, being duly sworn, deposes and states:

1. Declarant is a resident of CLARK County, NEVADA, over the age of 18, and competent to make this declaration.

2. Declarant is an attorney practicing law in the State of Nevada. Declarant has been retained to represent the interests of Heliodoro Magana, PA.

3. I am employed by the law firm John H. Cotton & Associates, which was retained to represent the interests of Heliodoro Magana, PA. At the time the firm was initially retained, attorney Eleanor Murphy, Esq., was assigned as the attorney primarily responsible for this case.

4. Ms. Murphy's employment with the firm ended abruptly in August of 2024. Review of business records indicates that Ms. Murphy did not file anything with the board to address the issues the firm was retained to address nor did she advise that she had not done so.

5. The firm first became aware of the failure to file a motion or petition on behalf of Mr. Magana when the firm received the Order to Show Cause several months later.

6. Upon being assigned this case, I diligently made efforts to investigate the current status of the case and ultimately determined that no motion or petition had been filed, at which time I promptly undertook the preparation of an appropriate petition. I offer this declaration in support of that petition.

7. Declarant is competent to testify as to the matters contained herein and furthermore acknowledges notice of the hearing on April 16, 2025, in Reno, Nevada, and intends to appear at that hearing with Mr. Magana.

8. This declaration is made subject to the laws of penalty of perjury of the State of Nevada.

Further the declarant sayeth naught.

__/s/*Brad J. Shipley*_____
BRAD SHIPLLEY ESQ.
NV Bar #12639

5P

FILED
MAR 2 6 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD, Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Frank A. Shallenberger, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS20566, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 1, 2023, the Nevada State Board of Medical Examiners (NSBME) and Respondent entered a settlement agreement in Case No. 23-7127-1, imposing discipline on Respondent's NSBME License No. 4951 to practice medicine for cause, relating in pertinent part to Respondent unlawfully prescribing a controlled substance for his own personal use.

3. Respondent failed to disclose to the Board the disciplinary order in NSBDE Case No. 23-7127-1 on his 2024 biennial renewal application for Certificate of Registration No. CS20566.

APPLICABLE LAW

4. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements federal and state law. 21 CFR § 1306.04(a); NRS 453.381(1).

5. It is a category E felony for an individual practitioner to dispense a substance included in schedule II, III or IV for the practitioner's own personal use except in a medical emergency. NRS 453.256(5) and (6).

6. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

7. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

9. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

10. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

11. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

12. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has furnished false or fraudulent material information in an application or committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(a) and (e) and NRS 453.241(1).

COUNT ONE

Violation of State Controlled Substances Act

13. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.256(5) and/or NRS 453.381(1) and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1 and by violating NRS 453.256(5) and/or NRS 453.381(1), Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4).

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COUNT THREE
Furnishing False Material Information to Board/
Obtaining Registration by False or Fraudulent Application

15. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 23-7127-1 on his 2024 biennial renewal application for Certificate of Registration No. CS20566, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a), NRS 453.241(1) and/or NRS 639.210(9), (10) and/or (12).

COUNT FOUR
Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 23-7127-1 by violating NRS 453.256(5) and/or NRS 453.381(1), Respondent has committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 26th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD,** **Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FRANK A. SHALLENBERGER, MD,** **Certificate of Registration No. CS20566,** **Respondent.**	**Case No. 23-515-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Frank A. Shallenberger, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Frank A. Shallenberger, MD
[redacted]
Carson City, NV [redacted]

Frank A. Shallenberger, MD
c/o Nevada Center
1231 Country Club Dr
Carson City, NV 89703

Lyn Beggs, Esq.
316 California Ave #863
Reno, NV 89509

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee :	$200.00
Convenience Fee :	$10.00
License Number :	CS20566
License Type :	Controlled Substance
New Expiration Date :	10/31/2026

Personal Information

First Name : FRANK

Middle (initial only) : A

Last Name : SHALLENBERGER

License # : CS20566

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Nevada Center

Military Address : ☐

Street : 1231 COUNTRY CLUB DR

Country : United States

City : CARSON CITY

State : Nevada

Zip : 89703

Practice Phone : (775) 884-3990

Cell Phone : [redacted]

Email Address : arleta@antiagingmedicine.cor

Sex : Male

Child Support Information – Check appropriate answer

- (●) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.
- ( ) Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)
- ( ) Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	(●) Yes ( ) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	( ) Yes (●) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	( ) Yes (●) No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state? ○ Yes ◉ No

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ○ Yes ◉ No

DEA Registration

Please upload a copy of your current DEA Registration associated with the Controlled Substance Registration you are renewing.

Document Name	Document Type	Date	Link	Action
DEA License	NV DEA Certificate	10/16/2024	Document Details	

Document Name :

Document Type : NV DEA Certificate

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload | Cancel

Acknowledgement and Declaration

☑ I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

By signing and submitting this renewal application, I certify that: 1. I hold an active and current Nevada license with my professional licensing board, and 2. My DEA certificate is CURRENT and reflects my current NV practicing address.

Signature : Frank Shallenberger

Date Of Application : 10/16/2024

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2024 to 10/31/2026	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : 120704713894

InvoiceDate : 10/16/2024

Paid

Pay & Submit

Nevada State Board of Pharmacy

Home Individual Renewal Reports Administration Company Inspection Compliance

Search Results

Last Name	First Name	License#	
SHALLEN...	FRANK	CS20566	○

First () Previous () 1 () Next () Last ()

Archive Delete

Individual Details

Personal () Address/Contact () Financial () Name () Education () Exam () DEA () Primary Board () Legal Info () NV Business () Child Support () Military () Acknowledgement () Employment () Application Data () License () Comment () Log () Correspondence () Document () Compliance () Fingerprints ()

Status : Active

Individual Details

Name	: SHALLENBERGER FRANK A
Individual ID	: 61577
DOB	: [redacted]
License#	: CS20566
Original Issue Date	: 10/29/2012
Mailing Address	: 1231 COUNTRY CLUB DR CARSON CITY,NV, 89706
Practice Phone	: (775) 884-3990
Home Phone	: [redacted]
Cell Phone	: [redacted]
Email Address	: doctor@antiagingmedicine.com

License Details

Controlled Substance - 11/01/2022 - 10/31/2024 - Active
Controlled Substance - 11/01/2020 - 10/31/2022 - Renewed
Controlled Substance - 11/01/2018 - 10/31/2020 -

Jser Portal

User Portal

Jnpaid Invoice - $0.00

First Name :* FRANK

Middle Name : A.

Suffix : -Select Suffixs-

SS# :* [redacted]

DOB :* [redacted]

Last Name :* SHALLENBERGER

Prefix : -Select Prefixs-

Gender : (•) Male ( ) Female

Age : [redacted]

Save Cancel

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **FRANK ANTHONY SHALLENBERGER, M.D., Respondent.**	**Case No. 23-7127-1** FILED DEC 01 2023 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Senior Deputy General Counsel for the Board and attorney for the IC, and Frank Anthony Shallenberger, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Lyn E. Beggs, Esq., of the Law Offices of Lyn E. Beggs, PLLC hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on January 7, 1984 (License No. 4951).

2. On April 21, 2023, in Case No. 23-7127-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges two (2) violations of NRS 630.301(4), Malpractice (Counts I and IV); three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II, III, and V); and one (1) violation of NRS 630.306(1)(c), Unlawful Prescribing of Controlled Substance or

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

Dangerous Drug (Count VI). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

3. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

4. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

5. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

6. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

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(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Counts II, III and V, three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records; and Count VI, one (1) violation of NRS 630.306(1)(c), Unlawful Prescribing of Controlled Substance or Dangerous Drug.

b. Respondent shall pay a fine of five thousand dollars ($5,000.00) within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement.

c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter, in the amount of nine thousand sixty-one dollars and seventy-three cents ($9,061.73), within 60 days of the Board's acceptance, adoption and approval of this Agreement.

d. The Respondent shall perform twenty-two (22) hours of Continued Medical Education (CME) related to best practices in prescribing, in addition to the required CMEs for licensure. These CME hours must be completed within one hundred eighty (180) days.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. The remaining counts of the Complaint, and any other claims arising from

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the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement

an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a). Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 20th day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 5th day of October 2023.

LAW OFFICES OF LYN E. BEGGS, PLLC

By _____

LYN E. BEGGS, ESQ.
316 California Ave., #863
Reno, NV 89509
Tel: (775) 432-1918
Email: lyn@lbeggslaw.com
Attorney for Respondent

DATED this 5 day of OCTOBER 2023.

By: _____

FRANK ANTHONY SHALLENGERGER, M.D.,
Nevada License No. 4951
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 23-7127-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 1st day of December, 2023.

DATED this 1st day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

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BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **FRANK ANTHONY SHALLENBERGER, M.D., Respondent.**	**Case No. 23-7127-1** FILED DEC 01 2023 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Senior Deputy General Counsel for the Board and attorney for the IC, and Frank Anthony Shallenberger, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Lyn E. Beggs, Esq., of the Law Offices of Lyn E. Beggs, PLLC hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on January 7, 1984 (License No. 4951).

2. On April 21, 2023, in Case No. 23-7127-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges two (2) violations of NRS 630.301(4), Malpractice (Counts I and IV); three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II, III, and V); and one (1) violation of NRS 630.306(1)(c), Unlawful Prescribing of Controlled Substance or

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

Dangerous Drug (Count VI). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

3. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

4. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

5. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

6. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

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(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Counts II, III and V, three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records; and Count VI, one (1) violation of NRS 630.306(1)(c), Unlawful Prescribing of Controlled Substance or Dangerous Drug.

b. Respondent shall pay a fine of five thousand dollars ($5,000.00) within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement.

c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter, in the amount of nine thousand sixty-one dollars and seventy-three cents ($9,061.73), within 60 days of the Board's acceptance, adoption and approval of this Agreement.

d. The Respondent shall perform twenty-two (22) hours of Continued Medical Education (CME) related to best practices in prescribing, in addition to the required CMEs for licensure. These CME hours must be completed within one hundred eighty (180) days.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. The remaining counts of the Complaint, and any other claims arising from

OFFICE OF THE GENERAL COUNSEL
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the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement

an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a). Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 20th day of October, 2023.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 5th day of October 2023.

LAW OFFICES OF LYN E. BEGGS, PLLC

By _____

LYN E. BEGGS, ESQ.
316 California Ave., #863
Reno, NV 89509
Tel: (775) 432-1918
Email: lyn@lbeggslaw.com
Attorney for Respondent

DATED this 5 day of OCTOBER 2023.

By: _____

FRANK ANTHONY SHALLENGERGER, M.D.,
Nevada License No. 4951
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 23-7127-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 1st day of December, 2023.

DATED this 1st day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

6

6A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: HIGH VIBES MEDICAL SUPPLY LLC

MDEG Physical Address: 3430 E FLAMINGO RD #301

City: LAS VEGAS State: NV Zip: 89121

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: 682-331-0707 Website: _____

Email: cecily.fernandez@icloud.com

Name of MDEG Administrator (NAC 639.694): Cecily Fernandez

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: walkers, canes, commodes
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:30am-4pm	■ Tue: 9:30am-4pm	■ Wed: 9:30am-4pm	■ Thurs: 9:30am-4pm	■ Fri: 9:30am-4pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Pending Medicare

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: n/a Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Cecily Fernandez

Business Name: HIGH VIBES MEDICAL SUPPLY LLC

Business Address: 3430 E FLAMINGO RD #301

City: LAS VEGAS State: NV Zip: 89121-5066

Telephone: 682-331-0707 Email: cecily.fernandez@icloud.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located** outside of this State **must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez

Print Name of Authorized Person Submitting Application

Cecily Fernandez

Original signature of Authorized Person (copies or stamps not accepted)

01/24/2025

Date

Board Use Only	Date Received: 1/28/25	Amount: $500-ck 1095564350

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/20/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Next First Insurance Agency, Inc.
PO Box 60787
Palo Alto, CA 94306

CONTACT NAME:
PHONE (A/C, No, Ext): (855) 222-5919 FAX (A/C, No):
E-MAIL ADDRESS: support@nextinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : State National Insurance Company, Inc.	12831
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
High Vibes Medical Supply LLC
3430 E Flamingo Rd Ste 301
Las Vegas, NV 89121

COVERAGES **CERTIFICATE NUMBER:** 753329044 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	X		NXT44CFKTR-00-GL	12/20/2024	12/20/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$1,000,000.00 $100,000.00 $15,000.00 $1,000,000.00 $2,000,000.00 $2,000,000.00 $
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ $ $ $ $
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE [ ]	$ $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] N / A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The Certificate Holder is Board of Certification/Accreditation. This Certificate Holder is an Additional Insured on the General Liability policy with respect to ongoing operations. All Certificate Holder privileges apply only if required by written agreement between the Certificate Holder and the insured, and are subject to policy terms and conditions.

CERTIFICATE HOLDER
Board of Certification/Accreditation
10461 Mill Run Cir Ste 1250
Owings Mills, MD 21117

LIVE CERTIFICATE
Click or scan to view

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **High Vibes Medical Supply LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/15/2024, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/11/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502115430353
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

100%

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: High Vibes Medical Supply LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3430 E Flamingo Rd

City: Las Vegas State: NV Zip: 89121

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 682-331-0707 Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Cecily Middle: G Last: Fernandez

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☐ F ☐ X

Mailing Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
National University		3/12 - 11/13	
Address	City	State	Zip
	San Bernardino	CA	92037
Diploma/Degree obtained, if any			
Masters in Counseling			

School Name		From - To (MM/YY – MM/YY)	
Cajon High School			
Address	City	State	Zip
	San Bernardino	CA	92411
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/23 to Current	[redacted]	Henderson	NV	[redacted]
8/23 to 4/24		Las Vegas	NV	
3/21 to 8/23		Fort Worth	TX	
5/15 to 3/21		Moreno Valley	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: High Vibes Therapy Circle			From - To (MM/YY – MM/YY): 1/23 to Current
Business Address: 3330 N Las Vegas	City: Las Vegas	State: NV	Zip: 89511
Phone: 682 331-0707	Title: ~~CEO~~ Owner		
Description of Duties: TeleHealth therapy			

Business Name: Dallas County Juvenile Detention			From - To (MM/YY – MM/YY): 3/21 to 1/23
Business Address: 2600 Lone Star dr	City: Dallas	State: TX	Zip: 75212
Phone: 214 698-2220	Title: Supervisor		
Description of Duties: Supervising staff, Safety & security			

Business Name: San Bernardino County CFS			From - To (MM/YY – MM/YY): 1/18 to 3/21
Business Address: 1032 s E street	City: San Bernardino	State: CA	Zip: 92408
Phone: 909-388-1900	Title: Investigator		
Description of Duties: Caseload, Investigations, Removals, Placements			

Business Name: San Bernardino County Department of Bhavioral			From - To (MM/YY – MM/YY): 1/15 to 1/18
Business Address: 303 E Vanderbilt way	City: San Bernardino	State: CA	Zip: 92415
Phone: 888-743-1478	Title: Therapist		
Description of Duties: Mental Health Services			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address.	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/25/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez

Print Name (First, Last)

Cecily Fernandez 1/25/25

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Cecily Fernandez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cecily Fernandez 1/25/25

Original Signature **Date**

Subscribed and Sworn to before me this 25 day of Jan, 2025

Ben Gill

Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
BEN GILL
My Appointment Expires
July 9, 2025
No. 16-1938-1

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG High Vibes Medical Supply LLC MDEG License # (if applicable) _____

Physical Address 3430 E Flamingo Rd ste 301

City Las Vegas State NV Zip 89121

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 682-331-0707 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Cecily Middle Ginnel Last Fernandez

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: National University			From - To (MM/YY – MM/YY): 3/12 - 11/13
Address	City: San Bernardino	State: CA	Zip: 92037
Diploma/Degree obtained, if any			

School Name: Cajon High School			From - To (MM/YY – MM/YY)
Address	City: San Bernardino	State: CA	Zip: 92411
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24 to Current	[redacted]	Henderson	NV	[redacted]
5/23 to 4/24		Las Vegas	NV	
3/21 to 5/23		Fort Worth	TX	
5/15 to 3/21		Moreno Valley	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
High Vibes Medical Supply LLC			10/24 to Current	
Business Address		**City**	**State**	**Zip**
3430 E Flamingo Rd		Las Vegas	NV	89121
Phone	**Title**		**Number of Employed Hours**	
682-331-0707	Manager		480	
Description of Duties	Direct Client services, Selling Medical Supplys			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
High Vibes Therapy Circle		1/23 to Current
Business Address	**City**	**State / Zip**
3330 N Las Vegas	Las Vegas	NV 89611
Phone	**Title**	**Number of Employed Hours**
682-331-0707	Owner	40
Description of Duties	Tele Health Therapy	

Business Name		From - To (MM/YY – MM/YY)
Dallas County Juvenile Dentention		3/21 to 1/23
Business Address	**City**	**State / Zip**
2600 Lone Star dr	Dallas	TX 75212
Phone	**Title**	**Number of Employed Hours**
214-498-2220	Supervisor	40
Description of Duties	Supervising staff, safety & security	

Business Name		From - To (MM/YY – MM/YY)
San Bernardino County Children and Family		1/18 to 3/21
Business Address	**City**	**State / Zip**
1032 s E street	San Bernardino	CA 92408
Phone	**Title**	**Number of Employed Hours**
909 388-1900	Investigator	40
Description of Duties	Investigations, Removals, Placement	

Business Name		From - To (MM/YY – MM/YY)
San Bernardino County Department of Behavior		11/15 to 1/18
Business Address	**City**	**State / Zip**
303 E Vanderbilt way	San Bernardino	CA 92415
Phone	**Title**	**Number of Employed Hours**
448-743-1478	Therapist	40
Description of Duties	Mental Health Services	

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State / Zip**
Phone	**Title**	**Number of Employed Hours**
Description of Duties		

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Cindy J — 1/25/25

Original Signature (electronic, copies or stamps not accepted) Date

I, Cecily Fernandez, **certify that as the MDEG Administrator for** High Vibes Medical Supply LLC,

that I (initial that you have read and meet the following requirements):

1. CF Have a high school diploma or its equivalent;
2. ____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez
Print Name (First, Last)

Cecily F
Original Signature (electronic, copies or stamps not accepted)

1/25/25
Date

Board Use Only	Date Received: 1/28/25

6B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ■ Nevada ☐ Out of State

[a]Is the business also a wholesaler? (NRS 639.016) ☐ Yes ■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Med Way Medical, Inc.

MDEG Physical Address: 3595 E PATRICK LN STE 300

City: LAS VEGAS State: NV Zip: 89120-6221

Mailing Address (if different from physical address): 555 E North Lane Suite 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 8773574407 Website: www.adapthealth.com

Email: credentialing@adapthealth.com

Name of MDEG Administrator (NAC 639.694): Michael Williams

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
NA ☒ Patients by prescriptions	■ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	☐ Life sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Wheelchairs, hospital beds
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Steven Distefano
	Telephone: 8773574407

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9 AM to 5:30 P	■ Tue: 9 AM to 5:30 P	■ Wed: 9 AM to 5:30 P	■ Thurs: 9 AM to 5:30	■ Fri: 9 AM to 5:30 PM
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(l))
None

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: None Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Utah

Parent Company (if any): Medstar Surgical & Breathing Equipment Inc Tax ID: 11-2959177

Corporation/Organization Name: Med Way Medical, Inc.

Mailing Address: 555 E North Lane Suite 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 4582255650 Email: credentialing@adapthealth.com

Contact Person Name: Natascha Amster

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3[g] who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person other **than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Natascha Amster

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01.02.2025

Date

Board Use Only	Date Received: 1/6/25	Amount: $500.00

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **MED WAY MEDICAL, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/12/2024, and in good standing in this State.

I further certify that the above FOREIGN CORPORATION (80) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/13/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202411135183829
You may verify this certificate online at https://www.nvsilverflume.gov/home

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/25/2024

5/17/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies, LLC 1185 Avenue of the Americas, Suite 2010 New York NY 10036 646-572-7300	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1434385 Med Way Medical Inc 3595 E PATRICK LN STE 300, LAS VEGAS NV 89120-6221	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Benchmark Insurance Company — 41394 INSURER B: Hartford Fire Insurance Company — 19682 INSURER C: Hartford Accident and Indemnity Company — 22357 INSURER D: Twin City Fire Insurance Company — 29459 INSURER E: XL Specialty Insurance Company — 37885 INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 21178644 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	N	N	D1023 G6279-5	5/17/2024	5/17/2025	EACH OCCURRENCE $ $1,000,000 DAMAGE TO RENTED PREMISES (Ea occurrence) $ $1,000,000 MED EXP (Any one person) $ $10,000 PERSONAL & ADV INJURY $ $1,000,000 GENERAL AGGREGATE $ $3,000,000 PRODUCTS - COMP/OP AGG $ $3,000,000 $
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] HIRED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] NON-OWNED AUTOS ONLY	N	N	39 CSE S65401	5/17/2024	5/17/2025	COMBINED SINGLE LIMIT (Ea accident) $ $1,000,000 BODILY INJURY (Per person) $ XXXXXXX BODILY INJURY (Per accident) $ XXXXXXX PROPERTY DAMAGE (Per accident) $ XXXXXXX $ XXXXXXX
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [X] CLAIMS-MADE [ ] DED [ ] RETENTION $	N	N	UM1023 6280-5	5/17/2024	5/17/2025	EACH OCCURRENCE $ 15,000,000 AGGREGATE $ 15,000,000 $ XXXXXXX
C D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below		N	39 WN S65400 39 WBR S65402 (MA & WI)	5/17/2024 5/17/2024	5/17/2025 5/17/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT $ $1,000,000 E.L. DISEASE - EA EMPLOYEE $ $1,000,000 E.L. DISEASE - POLICY LIMIT $ $1,000,000
E	Crime-Fidelity	N	N	ELU200697-24	11/8/2024	11/8/2025	$3,000,000/Ret: $50,000
A	Professional Liability			D1023 G6279-5	5/17/2024	5/17/2025	$1,000,000 occ/$3,000,000 agg

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

21178644
Evidence of Insurance

CANCELLATION See Attachment

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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220 W. Germantown Pike, Suite 250, Plymouth Meeting, PA 19462-1437
adapthealth.com P: 610-424-4515 E: licensing@adapthealth.com

Wednesday, January 8, 2025

Medstar Surgical &
Breathing Equipment Inc
Tax ID: 11-2959177

100% Owner of

Med Way Medical, Inc
Tax ID: 20-4941789

Corporate Officers
Wendy Russalesi; Chief Compliance Officer
[redacted]
TOMS RIVER, NJ [redacted]
[redacted]
wendy.russalesi@adapthealth.com

For questions or additional information, please contact me at the below email or phone.

Natascha Amster
Licensing & Governmental Credentialing Specialist, AdaptHealth
adapthealth
E: natascha.amster@adapthealth.com
P: 458-225-5650
www.adapthealth.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Med Way Medical, Inc. MDEG License # (if applicable): Pending

Physical Address: 3595 E PATRICK LN STE 300

City: LAS VEGAS State: NV Zip: 89120-6221

Mailing Address (if different from physical address): 555 E North Lane, Suite 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 458.225.5650 Website: www.adapthealth.com

Licensing Company Email: credentialing@adapthealth.com

Section 2: Personal Information

First: Michael Middle: Christian Last: Williams

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Salt Lake State: Ut Zip: [redacted]

Telephone: [redacted] Email: michael.williams1@adapthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Granger High School		09/2006-05/2008	
Address	**City**	**State**	**Zip**
3580 3600 W	West Valley	Ut	84119
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Brighton High School		09/2005-05/2006	
Address	**City**	**State**	**Zip**
2220 Bengal Blvd	Cottonwood Heights	Ut	84121
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2025-Present	[redacted]	Henderson	NV	[redacted]
10/24-02/25		Taylorsville	UT	
09/23-09/24		West Valley	UT	
01/20-08/23		Salt Lake City	UT	
01/19-01/20		Millcreek	UT	
09/14-01/19		West Valley	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Kristy Zigenis

From: Michael Williams <michael.williams1@adapthealth.com>
Sent: Wednesday, March 19, 2025 11:50 AM
To: Kristy Zigenis
Cc: Austin Drushal
Subject: Medway Medical MDEG administrator follow up

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good afternoon,

I wanted to follow up and apologize for not providing a more detailed description earlier regarding my experience with medical equipment.

During my time at Cottonwood Treatment Center as the Coordinator & Medical Device Trainer (September 2012 – May 2016), I worked extensively with a variety of medical equipment, including wheelchairs, walkers, nebulizers, oxygen concentrators, and portable oxygen concentrators. I led training sessions for new hires on the proper use of this equipment, ensuring staff were confident with both basic operations and troubleshooting protocols. I worked closely with the nursing team to ensure proficiency and provided daily, on-the-floor support for any device-related issues. Depending on onboarding needs and equipment-related concerns, approximately 15% to 25% of my shift was dedicated to managing and supporting these devices to ensure continuous patient care and equipment readiness.

Additionally, I wanted to note that my current hours worked with Med Way have recently increased—from 877 to 1,030.

Thank you for your consideration of my MDEG Administrator application. I truly appreciate your time and the opportunity to share more about my background.

Please don't hesitate to reach out if you need any further details—I'd be happy to assist.

Best regards, Michael Wiliams

Secured by Paubox - HITRUST certified

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medway Medical			10/2024-03/2025	
Business Address		**City**	**State**	**Zip**
1837 S 4130 W		Salt Lake	Ut	84104
Phone	**Title**		**Number of Employed Hours**	
801-791-6276	Medical Equipment Technician		877	
Description of Duties				
Medical Equipment Technicians are responsible for ensuring safe delivery, providing setup, and education in usage of home medical equipment for our customers. Setup is done in their home, long-term care setting, clinic or any location deemed necessary to service patients				

Business Name			From - To (MM/YY – MM/YY)	
Cottonwood Treatment Center			09/2012-05/2016	
Business Address		**City**	**State**	**Zip**
1144 W 3300 S		Salt Lake	Ut	84119
Phone	**Title**		**Number of Employed Hours**	
NA	Care Coordiator		7,626	
Description of Duties				
Managed patients health care plan by coordinating communication between patient, family, and various healthcare providers, facilitating access to necessary services, educating patients about their conditions, and monitoring progress				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

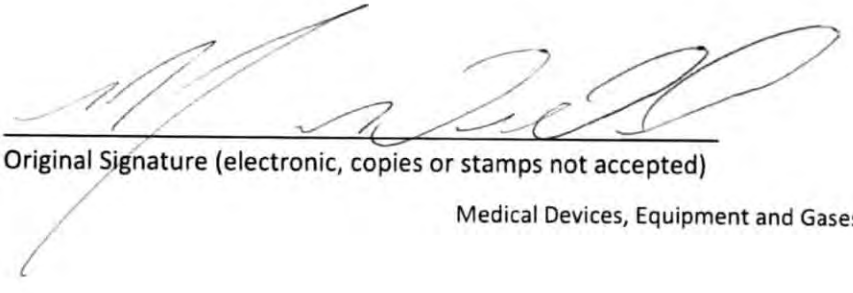
Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08-13-2011	11-28-2011	Ut	Taylorsville	Salt Lake
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
81100941		Taylorsville Justice Court		
Reason/Charge				
Theft				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
NA			NA	
Name of Business/Industry/Entity				
Dee's Family Restauraunt				

Provide explanation below:

I was 18 years of age when after a schol dance went out to eat with a group of friends upon finishing meal, I was told everything had been paid for. While standing outside waitress came out and informed me the meal had not been paid for. I told her I would pay for my meal but wouldnt be able to cover the full dinning ticket. She informed me she would call the police if the bill wasn't taken care in full. When the officer arrived I was given a ticket and told to appear in court. I plead guilty due to not knowing my rights or having any form of legal council. I am currently in the process of having this expunged.



Original Signature (electronic, copies or stamps not accepted)

02-18-2025

Date

I, Michael Chrisitan Williams, **certify that as the MDEG Administrator for**

Med Way Medical, Inc.,

that I (initial that you have read and meet the following requirements):

1. MW Have a high school diploma or its equivalent;
2. MW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael,Williams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02-18-2025

Date

Board Use Only	Date Received:

Acknowledgment Letter for MDEG License Application – State of Nevada

Michael C Williams

Branch Manager

Med Way Medical, Inc

[redacted] Henderson, NV, [redacted]

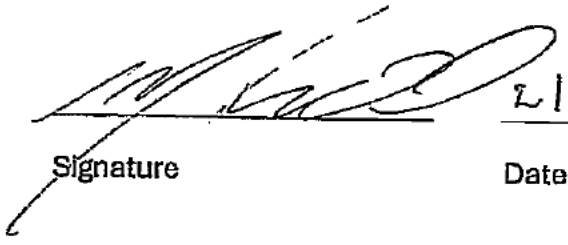
Thank you for your consideration of my MDEG Administrator application. I want to express my appreciation and gratitude for your time.

I acknowledge that I meet the required criteria for the Medical Devices, Equipment, and Gases (MDEG) Administrator role as defined in NAC 639.694. Specifically, have at least 1,500 hours of verifiable work experience and employed by a medical products provider or medical products whole seller at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week.

Again, I would like to express my utmost appreciation and gratitude for reviewing my MDEG Administrator application for the Great State of Nevada.

Thank you,

Michael Williams — Print

 — Signature

2/18/25 — Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Med Way Medical, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Pending

Physical Address: 3595 E PATRICK LN STE 300

City: LAS VEGAS State: NV Zip: 89120-6221

Mailing Address (if different from physical address): 655 E North Lake Suite 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 458-225-5650 Website: www.adapthealth.com

Licensing Company Email: credentialing@adapthealth.com

Section 2: Personal Information

First: Wendy Middle: Ann Last: Russalesi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Toms River State: NJ Zip: [redacted]

Telephone: [redacted] Email: wendy.russalesi@adapthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "Yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Thomas Edison State University		03/2004	
Address	City	State	Zip
111 W State St	Trenton	NJ	08608
Diploma/Degree obtained, if any			
Bachelors - Business Administration			
School Name		From - To (MM/YY – MM/YY)	
Woodbridge High School		09/1984 - 06/1988	
Address	City	State	Zip
1 Samuel Lupo Place	Woodbridge	NJ	07095
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2022-Current	[redacted]	Toms River	NJ	[redacted]
07/2013-06/2022	[redacted]	Jackson	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
AdaptHealth		07/2013-Current	
Business Address	**City**	**State**	**Zip**
220 W. Germantown Pike, Suite 250	Plymouth Meeting	PA	19462-1437
Phone	**Title**		
610-424-4515	Chief Compliance Officer		
Description of Duties			
design and implement internal controls to ensure compliance with applicable laws and regulations.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty but mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wendy Russalesi

Print Name (First, Last)

Wendy Russalesi

Original Signature (electronic, copies or stamps not accepted)

12/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Wendy Russalesi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Wendy Russalesi

Original Signature

12/27/2024

Date

Subscribed and Sworn to before me this 27th day of December

Natascha

Notary Public Signature

NATASCHA AMSTER
Commission # HH 093965
Expires February 17, 2025
Bonded Thru Troy Fain Insurance 800-385-7019

(Seal)

7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Boxout, LLC

Physical Address: 625 Ptttsburgh Ave, Suite 110

City: Mccarran State: NV Zip: 89437

Mailing Address (if different from physical address): 6333 Hudson Crossing Pkwy

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Name of Designated Representative (DR): Dennis Partain

Licensing Company Email: compliance@boxouthealth.com DR Email: dennis.partain@boxouthealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Obagi Cosmeceuticals, LLC
Address: 3760 Kilroy Airport Way STE 500 City: Long Beach State: CA Zip: 90806

Name: Capital Wholesale Drug Company
Address: 873 Williams Ave City: Columbus State: OH Zip: 43212

Name: InSource, Inc.
Address: 80 Summit View Lane City: Bastian State: VA Zip: 24314

Name: Medline Industries, LP
Address: Three Lakes Drive City: Northfield State: IL Zip: 60093

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ohio
Parent Company (if any): Boxout Group, LLC
Corporation/Organization Name: Boxout, LLC
Mailing Address: 6333 Hudson Crossing Pkwy
City: Hudson State: OH Zip: 44236
Telephone: 833-462-7746 Email: compliance@boxouthealth.com
Contact Person Name: Matthew Miller, Compliance Manager

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓ N/A	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see included memo on full disciplinary action with respect to the company, Boxout, LLC.

Original Signature (electronic, copies or stamps not accepted)

1-14-2023
Date

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson Ohio 44236
www.boxouthealth.com

January 3rd, 2024

Disciplinary History Summary and Brief Description

Boxout, LLC has had the following disciplinary actions from State Boards of Pharmacy. Boxout, LLC has previously operated under the names Boxout, LLC (fka WBC Group, LLC), MDC Acquisition Company, and WBC Group, LLC.

Arkansas BOP, January 6th, 2010

MDC Acquisition Company was contacted by the Arkansas State Board of Pharmacy regarding the shipment of prescription drugs into the State of Arkansas without licensure in response to the applications of said license permits for its Ohio and California facilities. MDC Acquisition Company resolved this matter, without an admission of guilt, by signing Consent Agreements on January 6th, 2010, and paid a penalty of $1000 per facility.

Alabama BOP, July 17th, 2018

WBC Group, LLC was contacted by the Alabama State Board of Pharmacy regarding a complaint of distributing prescription medical devices into the State of Alabama without *renewing its permits* (Permit 194118 and 194218, for OH and FL, respectively). WBC Group, LLC resolved this matter by signing Consent Orders on July 17th, 2018, and paid a penalty of $2500.00 per permit.

Colorado BOP, September 29, 2020

Boxout, LLC received was contacted by the Colorado Board of Pharmacy for failing to notify the board of a change in company name within the required 30-day period. This failure to notify applied to Boxout's Ohio and California facilities (WHO.8341 and WHO.8407). Boxout, LLC informally resolved this matter by signing a Final Agency Order on September 29, 2020, and paid a fee of $1,150.00 per license.

Alabama BOP, March 30, 2021

Boxout, LLC was contacted by the Alabama Board of Pharmacy regarding a *failure to disclose* the Colorado Final Agency Orders (listed above) on the Alabama permit renewal for its Ohio facility (AL license number: 194118). A Consent Order was signed and fully executed on March 30, 2021, to resolve the matter and a $1,000.00 fine was paid.

Ohio BOP, April 23, 2021

Boxout, LLC was contacted by the Ohio State Board of Pharmacy regarding the *sale of a prescription drug to a clinic that had a lapsed license*. Boxout had already put protections into place to prevent recurrence. Boxout signed a Settlement Agreement on April 23, 2021, to resolve the matter, and a $125.00 fine was paid.

I attest that the information provided herein is true and correct to the best of my knowledge and it is recognized that providing false information may result in disciplinary action.

Matthew J Miller
Regulatory Affairs & Compliance Manager

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I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Boxout, LLC

Facility Name

Matthew J Miller

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/14/2025

Date

Board Use Only	Date Received: 1/21/25	Amount: $1000 ch 26 3358

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson Ohio 44236
www.boxouthealth.com

Corporate Leadership Contact Information

Officers / Shareholders

1/15/2025

Officers						
Name	**Title**	**Number and Street Address**	**City**	**State**	**Zip**	**% of Ownership**
Ron M. Harrington	CEO, Owner	[redacted]				
Jill Harrington	Secretary					
Kurt Packer	President					
Geraldine Miller	Vice-President					
Kenneth Kramer	CFO					

various key employees - 5.6%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

BOXOUT, LLC

Organizational Documents on File	Filing Date
Registration – Foreign LLC	01/03/2025

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence BOXOUT, LLC, as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 01/03/2025, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/20/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202501205366471
You may verify this certificate online at
https://www.nvsilverflume.gov/home

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show BOXOUT, LLC, an Ohio Limited Liability Company, Registration Number 980052, was organized in the State of Ohio on May 29, 1997, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 27th day of November, A.D. 2024.

Ohio Secretary of State

Validation Number: 202433202450

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson Ohio 44236
www.boxouthealth.com

DEA – Not Applicable

Copy of DEA certificate is not applicable to our company because Boxout, LLC does not handle controlled substances of any kind.

1/15/2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. LHM/673441

Application/License No. _____

Boxout, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 625 Pittsburgh Ave. Suite 110, McCarran, NV 89437-6508 (Address of Applicant/Principal), as PRINCIPAL, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND (Surety Company), a corporation organized under the laws of the state of Maryland (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1299 Zurich Way Schaumburg, IL 60196-1056 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 16th, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of January, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Bond No. LPM7673441

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by **Robert D. Murray, Vice President**, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint **Jeremy BRYANT, Erin COBB, Randi DURITSKY, Anthony GIELTY, Stacey RICHARDS and Christopher ANDERSON, all of Cleveland, Ohio, EACH** its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings**, and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND**, this 6th day of February, A.D. 2019.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: *Robert D. Murray*
Vice President

By: *Dawn E. Brown*
Secretary

State of Maryland
County of Baltimore

On this 6th day of February, A.D. 2019, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officers of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2019

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8. Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify or revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Secretary of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney ...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 17th day of January 2025

SEAL

By: Brian M. Hodges
Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
www.reportsfclaims@zurichna.com
800-626-4577

BOXOGRO-01 LFANTA

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 2/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Sarah Modrell
Acrisure Great Lakes Partners Insurance Services, LLC 223 West Grand River Ave #1 Howell, MI 48843	PHONE (A/C, No, Ext): (216) 658-7843 FAX (A/C, No): E-MAIL ADDRESS: semodrell@acrisure.com

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Boxout Group, LLC 6333 Hudson Crossing Parkway Hudson, OH 44236	INSURER A : Atlantic Specialty Insurance Company	27154
	INSURER B : National Casualty Company	11991
	INSURER C : Medmarc Casualty Insurance Company	22241
	INSURER D : Everest Indemnity Insurance Company	10851
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER: 24-25** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR			7110148130009	6/1/2024	6/1/2025	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	15,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	
	OTHER:							$	
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO			7110148130009	6/1/2024	6/1/2025	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
							Comp/Coll. Ded.	$	1,000
A	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	20,000,000
	EXCESS LIAB CLAIMS-MADE			7110148130009	6/1/2024	6/1/2025	AGGREGATE	$	20,000,000
	DED X RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A			WCC 343115 A	6/1/2024	6/1/2025	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Products Liability			24OH380005	6/1/2024	6/1/2025	Each Claim/Aggregate		10,000,000
D	Excess Products Liab			LS9EX00090-241	6/1/2024	6/1/2025	Each Claim/Aggregate		10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Ref: 625 Pittsburgh Ave, Ste 110
McCarran, NV
89437-6508

CERTIFICATE HOLDER

FOR INFORMATIONAL PURPOSES ONLY

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Boxout, LLC MDEG License # (if applicable) N/A

Physical Address 625 Pittsburgh Ave, Ste 110

City McCarran State NV Zip 89437

Mailing Address (if different from physical address) 6333 Hudson Crossing Pkwy

City Hudson State OH Zip 44236

Telephone 909-289-5164 Website www.boxouthealth.com

Licensing Company Email Compliance@boxouthealth.com

Section 2: Personal Information

First Dennis Middle Steven Last Partain II

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Redlands State _____ Zip [redacted]

Telephone [redacted] Email Dennis.Partain@boxouthealth.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
London School of Economics		08/11 - 06/12	
Address	City	State	Zip
	London, UK		
Diploma/Degree obtained, if any			
Master's of Science China Comparative Perpective			

School Name		From - To (MM/YY – MM/YY)	
University of Redlands		08/05 - 06/10	
Address	City	State	Zip
	Redlands	CA	92374
Diploma/Degree obtained, if any			
B.S. Global Business			

School Name		From - To (MM/YY – MM/YY)	
University of Redlands		08/05 -06/10	
Address	City	State	Zip
Diploma/Degree obtained, if any			
B.A. Asian Studies			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 - Present	[redacted]	Redlands	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/13 - 05/18		Highland	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Boxout, LLC			07/22 - Present
Business Address	**City**	**State**	**Zip**
1560 S Baker Ave, Ste A	Ontario	CA	91761
Phone	**Title**	**Number of Employed Hours**	
833-462-7746		6500	
Description of Duties			
Manage Distribution Centers in California and Texas.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Dan

Original Signature (electronic, copies or stamps not accepted)

3/26/2025

Date

I, Dennis Steven Partain II, **certify that as the MDEG Administrator for**

Boxout, LLC,

that I (initial that you have read and meet the following requirements):

1. DP Have a high school diploma or its equivalent;
2. DP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dennis Partain

Print Name (First, Last)

Dennis

Original Signature (electronic, copies or stamps not accepted)

3/26/2025

Date

Board Use Only	Date Received: 3/27/25

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson Ohio 44236
www.boxouthealth.com

February 19th, 2025

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, NV 89521

Dear Board of Pharmacy,

Dennis Partain II will be moving from Redlands, CA to the Reno area to oversee Operations and to perform the duties of the Designated Representative at the new Distribution Center located at:

625 Pittsburgh Ave, Ste 110
Mccarran, NV 89437-6508

Dennis will be at the facility prior to engaging in the distribution of dangerous drugs.
Once his home address is known we will promptly update the Board with this information.

Please do not hesitate to contact me if you have any questions.

Respectfully,

Matthew

Matthew J Miller
Regulatory Compliance Manager
Phone: 833-462-7746 Ext. 5025
MatthewMiller@boxouthealth.com
www.boxouthealth.com

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Boxout, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 625 Pittsburgh Ave

City McCarren Mccarran Dr State NV Zip 89437-6508

Mailing Address (if different from physical address) 6333 Hudson Crossing Pkwy

City Hudson State OH Zip 44236-4346

Telephone 833-462-7746 Website www.boxouthealth.com

Licensing Company Email compliance@boxouthealth.com

Section 2: Personal Information

First Dennis Middle Steven Last Partain II

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Redlands State CA Zip [redacted]

Telephon [redacted] Email dennis.partain@boxouthealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: London School of Economics			From - To (MM/YY – MM/YY): 08/2011 - 06/2012
Address	City: London, UK	State	Zip
Diploma/Degree obtained, if any: Master's in Science China in Comparative Perspective			
School Name: University of Redlands			From - To (MM/YY – MM/YY): 08/2005 - 06/2010
Address	City: Redlands	State: CA	Zip: 92374
Diploma/Degree obtained, if any: B.S. Global Business			
School Name: University of Redlands			From - To (MM/YY – MM/YY): 08/2005 - 06/2010
Address	City: Redlands	State: CA	Zip: 92374
Diploma/Degree obtained, if any: B.A. Asian Studies			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 06/2018 - Present	[redacted]	City: Redlands	State: CA	Zip: [redacted]
From - To (MM/YY – MM/YY): 06/2013 - 05/2018	[redacted]	City: Highland	State: CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Boxout LLC				From - To (MM/YY – MM/YY): 07/2022 - Present
Business Address: 1560 S. Baker Avenue		City: Ontario	State: CA	Zip: 91761
Phone: 909-289-5164	Title: Director of West Coast Operations			Number of Employed Hours: 6,500
Description of Duties: Manage warehousing in California and Texas.				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson Ohio 44236
www.boxouthealth.com

12/30/2024

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy #206
Reno, NV 89521

Dear Board of Pharmacy,

We are pleased to announce that we are opening a new distribution center in McCarran, NV, and will be closing our facility in Ontario, CA. Our target date to begin shipping from the Nevada facility is April 1, 2025.
Dennis Partain, our current Director of West Coast Operations, will be transitioning from our California distribution center to the new Nevada facility and will fulfill the role of Designated Representative (DR). Mr. Partain has successfully managed our TX and CA facilities and has consistently worked an average of 50 hours per week. As of now, he has accumulated approximately 6,000 hours of experience in his role at Boxout, LLC., and this total will increase significantly by the planned shipping start date.

This attestation is being provided to fulfill the requirement for the hours needed for the DR application. Mr. Partain's hire date was July 25, 2022.

Thank you for your attention to this matter. If you need any further information or documentation, please do not hesitate to reach out.

Attested to by:

Name: Dennis Partain

Title: Director West Coast Operation

Signature Dennis

Person Having Direct Knowledge of Applicants Work Experience (Direct Supervisor)

Name: Andy Hinkle

Title: Vice President of Operations

Signature

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Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Dennis Steven Partain II, **certify that as the designated representative for**

Boxout, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. II I am at least 21 years of age;
3. II I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. II I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. II I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. II I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. II I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dennis Steven Partain II

Print Name (First, Last)

Dennis

Original Signature (electronic, copies or stamps not accepted)

1/2/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dennis Steven Partain II

Print Name (First, Last)

Dennis

Original Signature (electronic, copies or stamps not accepted)

1/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Bernardino

I, Dennis Steven II Partain, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Dennis

Original Signature

1/6/25

Date

Subscribed and Sworn to before me this 6th day of January.

Rosita Barroso

Notary Public Signature

ROSITA BARROSO
Notary Public - California
San Bernardino County
Commission # 2385318
My Comm. Expires Dec 4, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Boxout, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 625 Pittsburgh Ave, Suite 110 rjm 1/9/2025

City: ~~McCarron~~ Mccarran rjm 1/10/2025 State: NV Zip: 89437-6508

Mailing Address (if different from physical address): 6333 Hudson Crossing Parkway

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Licensing Company Email: Compliance@boxouthealth.com

Section 2: Personal Information

First: Ronald Middle: M Last: Harrington

Alias(es, nicknames, name changes, etc.): Ron

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Hudson State: OH Zip: [redacted]

Telephone: [redacted] Email: Compliance@boxouthealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kenyon College		09/87- 05/91	
Address	City	State	Zip
104 College Drive	Gambier	OH	43022
Diploma/Degree obtained, if any			
History			

School Name		From - To (MM/YY – MM/YY)	
Western Reserve Academy		09/84 - 06/87	
Address	City	State	Zip
115 College Street	Hudson	OH	44236
Diploma/Degree obtained, if any			
College Prep			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2010 -Present	[redacted]	Hudson	OH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Boxout, LLC			05/97 - Present
Business Address	**City**	**State**	**Zip**
6333 Hudson Crossing Parway	Hudson	OH	44236
Phone	**Title**		
330-963-8650	CEO		

Description of Duties

Oversee overall operations, directing and delegating agendas, driving profitability and strategy.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Ms. Phaynarikone from the Nevada Board of Pharmacy clarified to Boxout, LLC by email on September 22, 2022, that questions four (4) through six (6) on Page 5 refer specifically to personal involvement of the officers, not the entire company.

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronald Harrington

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/25

Date

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of SUMMIT

I, Ronald Harrington, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/25

Date

Subscribed and Sworn to before me this 6th day of January.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Matthew J Miller
Notary Public, State of Ohio
My Commission Expires:
December 03, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Boxout, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 625 Pittsburgh Ave, Suite 110 mfm 1/8/2025

City: ~~McGarren~~ Mccarran mfm 1/10/2025 State: NV Zip: 89437-6508

Mailing Address (if different from physical address): 6333 Hudson Crossing Parkway

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Licensing Company Email: Compliance@boxouthealth.com

Section 2: Personal Information

First: Kenneth Middle: R Last: Kramer

Alias(es, nicknames, name changes, etc.): Ken

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Hudson State: OH Zip: [redacted]

Telephone: [redacted] Email: Compliance@boxouthealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kent State		6/1992-8/1993	
Address	City	State	Zip
800 E Summit St	Kent	OH	44240
Diploma/Degree obtained, if any			
MS, Accounting			

School Name		From - To (MM/YY – MM/YY)	
Ohio University		9/1988-6/1992	
Address	City	State	Zip
1 Ohio University Dr	Athens	OH	45701
Diploma/Degree obtained, if any			
BA, Finance			

School Name		From - To (MM/YY – MM/YY)	
High School			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/4- Present	[redacted]	Hudson	OH	[redacted]
From - To (MM/YY – MM/YY) N/A		City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Boxout, LLC			11/2019- Present
Business Address	**City**	**State**	**Zip**
6333 Hudson Crossing Parkway	Hudson	OH	44236
Phone	**Title**		
833-462-7746	Vice President		

Description of Duties

Oversee financial operations of Boxout, LLC. Also serve as the Compliance Officer.

Business Name			From - To (MM/YY – MM/YY)
CVS Health			5/2010-11/2019
Business Address	**City**	**State**	**Zip**
One CVS Drive	Woonsocket	RI	02895
Phone	**Title**		
401-765-1500	VP, Operations		

Description of Duties

Worked on Pharmacy Benefits Manager (PBM) side of the business.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Ms. Phaynarikone from the Nevada Board of Pharmacy clarified to Boxout, LLC by email on September 22, 2022, that questions four (4) through six (6) on Page 5 refer specifically to personal involvement of the officers, not the entire company.

Kenneth Kwan
Original Signature (electronic, copies or stamps not accepted)

1/6/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kenneth Kramer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of SUMMIT

I, Kenneth Kramer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2025

Date

Subscribed and Sworn to before me this 6th day of January.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Matthew J Miller
Notary Public, State of Ohio
My Commission Expires:
December 03, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Boxout, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 625 Pittsburgh Ave, Suite 110 mfa 1/8/2025

City: ~~McCarren~~ Mccarran mfa 1/10/2025 State: NV Zip: 89437-6508

Mailing Address (if different from physical address): 6333 Hudson Crossing Parkway

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Licensing Company Email: Compliance@boxouthealth.com

Section 2: Personal Information

First: Kurt Middle: Raymond Last: Packer

Alias(es, nicknames, name changes, etc.): Ken

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Hudson State: OH Zip: [redacted]

Telephone: [redacted] Email: Compliance@boxouthealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Akron			9/80-5/84	
Address		City	State	Zip
302 E Buchtel Ave		Akron	OH	44325
Diploma/Degree obtained, if any				
BS, Accounting				
School Name			From - To (MM/YY – MM/YY)	
Dover High School				
Address		City	State	Zip
520 N Walnut St		Dover	OH	44622
Diploma/Degree obtained, if any				
HS Diploma, College Prep				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16- Present	[redacted]	Chagrin Falls	OH	[redacted]
8/03-11/16	[redacted]	Hudson	OH	
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip
N/A	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Boxout, LLC			11/15 - Present	
Business Address		**City**	**State**	**Zip**
6333 Hudson Crossing Parway		Hudson	OH	44236
Phone	**Title**			
833-462-7746	Vice President			
Description of Duties				
Oversee financial operations of Boxout, LLC. Also serve as the Compliance Officer.				

Business Name			From - To (MM/YY – MM/YY)	
RGH Enterprises, Inc.			1/02-11/15	
Business Address		**City**	**State**	**Zip**
1810 Summit Commerce Park		Twinsburg	OH	44087
Phone	**Title**			
330-963-6998	President			
Description of Duties				
Worked on Pharmacy Benefits Manager (PBM) side of the business.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Ms. Phaynarikone from the Nevada Board of Pharmacy clarified to Boxout, LLC by email on September 22, 2022, that questions four (4) through six (6) on Page 5 refer specifically to personal involvement of the officers, not the entire company.

Original Signature (electronic, copies or stamps not accepted)

1/6/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kurt Packer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/4/2025

Date

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of SUMMIT

I, Kurt R. Packer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2025

Date

Subscribed and Sworn to before me this 6th day of January.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Matthew J Miller
Notary Public, State of Ohio
My Commission Expires:
December 03, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Boxout, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 625 Pittsburgh Ave, Suite 110 Mm 1/9/2025

City: ~~McCarren~~ Mccarran Mm 1/10/2025 State: NV Zip: 89437-6508

Mailing Address (if different from physical address): 6333 Hudson Crossing Parkway

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Licensing Company Email: Compliance@boxouthealth.com

Section 2: Personal Information

First: Geraldine Middle: A Last: Miller

Alias(es, nicknames, name changes, etc.): Gerrie

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☒ F ☐ X

Mailing Address: [redacted]

City: Hudson State: OH Zip: [redacted]

Telephone: [redacted] Email: Compliance@boxouthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Garfield Heights High School		09/87- 05/91	
Address	**City**	**State**	**Zip**
4900 Turney Road	Garfield Heights	OH	44125
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)		City	State	Zip
12/00-Present	[redacted]	Walton Hills	OH	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Boxout, LLC			05/97 - Present
Business Address	**City**	**State**	**Zip**
6333 Hudson Crossing Parway	Hudson	OH	44236
Phone	**Title**		
833-462-7746	Vice President		
Description of Duties			
Oversee overall operations, directing and delegating agendas, driving profitability and strategy.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Ms. Phaynarikone from the Nevada Board of Pharmacy clarified to Boxout, LLC by email on September 22, 2022, that questions four (4) through six (6) on Page 5 refer specifically to personal involvement of the officers, not the entire company.

Gerrie Miller
Original Signature (electronic, copies or stamps not accepted)

1-6-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Geraldine Miller

Print Name (First, Last)

Geraldine Miller — 1.6.25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of SUMMIT

I, Geraldine Miller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Geraldine Miller — 1.6.25

Original Signature — **Date**

Subscribed and Sworn to before me this 6th day of January.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Matthew J Miller
Notary Public, State of Ohio
My Commission Expires:
December 03, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Boxout, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 625 Pittsburgh Ave Suite 110, m/m 1/9/2025

City: ~~McCarren~~ Mccarran m/m 1/10/2025 State: NV Zip: 89437-6508

Mailing Address (if different from physical address): 6333 Hudson Crossing Parkway

City: Hudson State: OH Zip: 44236

Telephone: 833-462-7746 Website: www.boxouthealth.com

Licensing Company Email: Compliance@boxouthealth.com

Section 2: Personal Information

First: Jill Middle: Last: Harrington

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☒ F ☐ X

Mailing Address[redacted]

City: Hudson State: OH Zip [redacted]

Telephone[redacted] Email: Compliance@boxouthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hillsdale College		09/87- 05/91	
Address	City	State	Zip
33 E College St	Hillsdale	MI	49242
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/10- Present	[redacted]	Hudson	OH	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Boxout, LLC			05/97 - Present
Business Address	**City**	**State**	**Zip**
6333 Hudson Crossing Parkway	Hudson	OH	44236
Phone	**Title**		
330-592-4924	Secretary		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Ms. Phaynarikone from the Nevada Board of Pharmacy clarified to Boxout, LLC by email on September 22, 2022, that questions four (4) through six (6) on Page 5 refer specifically to personal involvement of the officers, not the entire company.

Jill Hamington
Original Signature (electronic, copies or stamps not accepted)

1/14/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jill Harrington

Print Name (First, Last)

Jill Harrington — 1/14/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of SUMMIT

I, JILL HARRINGTON, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jill Harrington — 1/14/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 14th day of January.

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

Matthew J Miller
Notary Public, State of Ohio
My Commission Expires:
December 03, 2029

(Seal)

BOXOUT
Empowering Health & Wellness

6333 Hudson Crossing Parkway
Hudson, Ohio 44236
www.boxouthealth.com

The following employees are working currently at our NV Distribution center:

Current Employees

Valerie Verona
MyaAlexandria Euotolia Zavala
Benito Garcia
Alberto Hernandez
Gabriel Lopez
Juan Flores
Seth Hixenbaugh
Diego Hernandez Reyes
Nevaeh Hernandez
Elijah Albert

The following employees are relocating from our CA Distribution Center:

CA Employees relocating

Eduardo Cervantes
Adrian Menera
Lilivet Morales
Yuri Valdovinos
Dennis Partain
Daniel Sanchez
Robert Anaya
Jeff Culkosky

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7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	■ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: The Tranzonic Companies

Physical Address: 5850 E North Belt Rd

City: Las Vegas State: NV Zip: 89135

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 858-776-6010 Website: http://www.tranzonic.com/

Name of Designated Representative (DR): Justin Nunez

Licensing Company Email: justin.nunez@acutecareonline.com DR Email: justin.nunez@acutecareonline.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	■ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	N/A

Reason/Charge
N/A

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

9/16/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cardinal Health
Address: PO Box 70539 City: Chicago State: IL Zip: 60873

Name: Avanos Medical
Address: PO Box 732583 City: Dallas State: TX Zip: 75373

Name: International Medical
Address: 2981 Gateway Drive City: Pompano Beach State: FL Zip: 33069

Name: Medline Industries
Address: Dept LA 21558 City: Pasedena State: CA Zip: 91185

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ohio
Parent Company (if any): Tranzonic Intermediate Holdings, Inc.
Corporation/Organization Name: The Tranzonic Companies
Mailing Address: 5850 E North Belt Rd
City: Las Vegas State: NV Zip: 89135
Telephone: 858-776-6010 Email: justin.nunez@acutecareonline.com
Contact Person Name: Justin Nunez

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

The Tranzonic Companies

Facility Name

Pat Fitzmaurice

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/16/24

Date

Board Use Only	Date Received: 10/7/24	Amount: $1000-ck10000017440

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Re: The Tranzonic Companies
Nevada Wholesaler Application

List of Officers and Directors

Robert Lawrence Kibbe Jr.
Director, President, and CEO

Patrick Fitzmaurice
Director, Vice President, Secretary, Treasurer, and CFO

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Re: The Tranzonic Companies
Nevada Wholesaler Application

List of all corporation shareholders and their percent ownership

Parent Company Name: Tranzonic Intermediate Holdings, Inc.
Parent Company Address: 26301 Curtiss Wright Parkway, Cleveland, OH 44143

Tranzonic Intermediate Holdings, Inc. is 100% owner of The Tranzonic Companies.

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show THE TRANZONIC COMPANIES, an Ohio corporation, Charter No. 197596, having its principal location in Cleveland, County of Cuyahoga, was incorporated on September 26, 1946 and is currently in GOOD STANDING upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 2nd day of October, A.D. 2024.

Ohio Secretary of State

Validation Number: 202427601332

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Re: The Tranzonic Companies
Nevada Wholesaler Application

Vendor List

Vendor Name	Address
Avanos Medical Inc	PO Box 732583, Dallas, TX 75373
Cardinal Health Medical Products and Services	PO Box 70539, Chicago, IL 60673
EMD Millipore Corp	25760 Network Place, Chicago, IL 60673
International Medical Ind, Inc	2981 Gateway Drive, Pompano Beach, FL 33069
Medline Industries, Inc	Dept LA 21558, Pasadena, CA 91185
McKesson Medical	PO Box 933027, Atlanta, GA 31193
MPS Pharma & Medical Inc	465 Berry St, Brea, CA 92821
Neomed Inc	2997 Cobb Pkwy, Unit 724081, Atlanta, GA 31139
Pro Medical Distribution LLC	11555 W 83rd Terrace, Lenexa, KS 66214
The Metrix Company	4400 Chavenelle Road, Dubuque, IL 52002

AGENCY CUSTOMER ID: 570000096559

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	The Tranzonic Companies
POLICY NUMBER	
See Certificate Number: 570109097571	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570109097571	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Schedule

The Tranzonic Companies
TZ Parent Holding LLC
TZ Acquisition Corp
Tranzonic Intermediate Holdings Inc
Hospital Specialty Company
HOSPECO
CCP Industries Inc
Plezall Wipers Inc
Cleancorps Company
J & L Work Apparrel
Care Cleaning and Protection
Nutrend
Adenna LLC
ERC Wiping Products
ERC Acquisition Inc
Nilodor Inc
High Tech Conversions LLC
Blue Thunder Technologies LLC
Air Delights, Inc.
ISO Med Inc.
Nuance Solutions
The Tranzonic Companies
Chemcor Chemical Corporation
Monarch Brands, Inc.
McGowan Enterprises, Inc. dba Acute Care Pharmaceuticals
Hospeco Brands Group

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CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 10/23/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
Cleveland OH Office
950 Main Avenue
Suite 1600
Cleveland OH 44113 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Navigators Specialty Insurance Company	36056
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
The Tranzonic Companies
26301 Curtiss Wright Parkway
Richmond Hts OH 44143 USA

COVERAGES **CERTIFICATE NUMBER:** 570109097571 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS,

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			CH24NP3Z0F4NXIC	09/30/2024	09/30/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$25,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	POLICY X PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) N/A						E.L. EACH ACCIDENT	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Suite 206
Reno NV 89521 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier :

Certificate No : 570109097571

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 3494190

Application/License No. _____

The Tranzonic Companies (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5850 E. North Belt Rd., Las Vegas, NV 89135 (Address of Applicant/Principal), as PRINCIPAL, and SureTec Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2103 CityWest Blvd., Suite 1300, Houston, TX 77042 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 02, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of October, 2024.

APPLICANT/PRINCIPAL

COMPANY
The Tranzonic Companies

Authorized Representative

SURETY

SureTec Insurance Company

Surety Company's Representative

Aaron P. Clark, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Tami Jones

Witness Nick Patetta

Countersigned by:

Nevada ~~Resident~~ Licensed Agent Robert Francis Bobo, Jr
NV License # 749488

POA# 4221319

JOINT LIMITED POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That SureTec Insurance Company, a Corporation duly organized and existing under the laws of the State of Texas and having its principal office in the County of Harris, Texas and Markel Insurance Company (the "Company"), a corporation duly organized and existing under the laws of the state of Illinois, and having its principal administrative office in Glen Allen, Virginia, does by these presents make, constitute and appoint:

Robert F. Bobo, Florence McClellan, Rachel Richardson, Aaron P. Clark, Craig C Payne, Laura Kneitz, Nick Patetta, Teresa D Kelly, Tami Jones, Erica Kneitz, Kala Lee, Timothy F Kelly

Their true and lawful agent(s) and attorney(s)-in-fact, each in their separate capacity if more than one is named above, to make, execute, seal and deliver for and on their own behalf, individually as a surety or jointly, as co-sureties, and as their act and deed any and all bonds and other undertaking in suretyship provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed the sum of:

Twenty Five Million and 00/100 Dollars ($25,000,000.00)

This Power of Attorney is granted and is signed and sealed under and by the authority of the following Resolutions adopted by the Board of Directors of SureTec Insurance Company and Markel Insurance Company:

"RESOLVED, That the President, any Senior Vice President, Vice President, Assistant Vice President, Secretary, Assistant Secretary, Treasurer or Assistant Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signature, which may be attested or acknowledged by any officer or attorney, of the company, qualifying the attorney or attorneys named in the given power of attorney, to execute in behalf of, and acknowledge as the act and deed of the SureTec Insurance Company and Markel Insurance Company, as the case may be, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto."

IN WITNESS WHEREOF, Markel Insurance Company and SureTec Insurance Company have caused their official seal to be hereunto affixed and these presents to be signed by their duly authorized officers on the 7th day of February , 2024 .

SureTec Insurance Company

By: _____
Michael C. Keimig, President

SURETEC INSURANCE COMPANY TEXAS

MARKEL INSURANCE CORPORATE SEAL COMPANY ILLINOIS

Markel Insurance Company

By: _____
Lindey Jennings, Vice President

State of Texas
County of Harris:

On this 7th day of February , 2024 A. D., before me, a Notary Public of the State of Texas, in and for the County of Harris, duly commissioned and qualified, came THE ABOVE OFFICERS OF THE COMPANIES, to me personally known to be the individuals and officers described in, who executed the preceding instrument, and they acknowledged the execution of same, and being by me duly sworn, disposed and said that they are the officers of the said companies aforesaid, and that the seals affixed to the proceeding instrument are the Corporate Seals of said Companies, and the said Corporate Seals and their signatures as officers were duly affixed and subscribed to the said instrument by the authority and direction of the said companies, and that Resolutions adopted by the Board of Directors of said Companies referred to in the preceding instrument is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand, and affixed my Official Seal at the County of Harris, the day and year first above written.

JULIE E MCCLARY
Notary Public State of Texas
Commission # 1294680-5
Commission Expires March 29, 2026

By: _____
Julie E. McClary, Notary Public
My commission expires 3/29/2026

We, the undersigned Officers of SureTec Insurance Company and Markel Insurance Company do herby certify that the original POWER OF ATTORNEY of which the foregoing is a full, true and correct copy is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, we have hereunto set our hands, and affixed the Seals of said Companies, on the 2nd day of October , 2024 .

SureTec Insurance Company

By: _____
M. Brent Beaty, Assistant Secretary

Markel Insurance Company

By: _____
Andrew Marquis, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity. 4221319
For verification of the authority of this Power you may call (713)812-0800 on any business day between 8:30 AM and 5:00 PM CST.

Scott Kipper, Commissioner of Insurance

Non-Resident Producer

Qualification Effective Dates

Casualty 04/11/2011 Property 04/11/2011

ROBERT FRANCIS BOBO JR

NPN: 7372840

LOCKTON
3657 BRIARPARK DR STE 700
HOUSTON, TX 77042-5264

is authorized to transact business as described above

License No: 749488 Issue Date: 04/11/2011 Expiration Date: 04/30/2026

Generated by Sircon 310691387

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

ROBERT FRANCIS BOBO JR
LOCKTON
3657 BRIARPARK DR STE 700
HOUSTON, TX 77042-5264

LICENSE NUMBER: 749488 NPN: 7372840

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer
Casualty, Property

Issue Date: 04/11/2011 Expiration Date: 04/30/2026

Generated by Sircon 310691387

Arch | Insurance

CHANGE RIDER

To be attached to and form a part of surety bond number SU 1196281, dated the 19th day of September, 2023, issued by Arch Insurance Company, a Missouri insurance company, as surety ("Surety"), on behalf of Iso-Med Inc., as principal (the "Principal"), in favor of State of Nevada and to the Nevada State Board of Pharmacy, as obligee (the "Obligee").

The Principal and the Surety hereby consent to changing the attached bond as follows:

Principal Name from: Iso-Med Inc.
to: The Tranzonic Companies dba ISO-MED

This change is effective the 23rd day of October, 2024. The attached bond shall be subject to all of its terms, conditions and limitations except as herein modified.

IN WITNESS WHEREOF, said Principal and Surety have caused these presents to be duly signed and sealed this 4th day of November, 2024.

WITNESS / ATTEST

The Tranzonic Companies dba ISO-MED
(Principal)

By: Pat FitzMaurice, CFO (Seal)
Name:
Title:

ARCH INSURANCE COMPANY
(Surety)

By: (Seal)
Daisy Greathouse, Attorney-in-Fact

ACCEPTED:

(Obligee)

By: (Seal)
Name:
Title:
Date:

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Aaron P. Clark, Craig C. Payne, Daisy Greathouse, Erica Kneitz, Florence McClellan, Kala Lee, Laura Kneitz, Nick Patetta, Rachel Richardson, Robert F. Bobo, Tami Jones, Teresa D. Kelly and Timothy F. Kelly of Houston, TX (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding One Hundred Fifty Million Dollars ($150,000,000.00). This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on August 31, 2022, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:
"**VOTED**, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on August 31, 2022:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on August 31, 2022, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **15th day of September, 2023**.

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company CORPORATE SEAL 1971 Missouri

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

Commonwealth of Pennsylvania - Notary Seal
MICHELE TRIPODI, Notary Public
Philadelphia County
My Commission Expires July 31, 2025
Commission Number 1168622

Michele Tripodi, Notary Public
My commission expires 07/31/2025

CERTIFICATION

I, **Regan A. Shulman**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated September 15, 2023** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 4th **day of** November, **20**24.

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

Arch Insurance Company CORPORATE SEAL 1971 Missouri

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com
Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: The Tranzonic Companies — MDEG License # (if applicable): N/A

Physical Address: 5850 E North Belt Rd

City: Las Vegas — State: NV — Zip: 89135

Mailing Address (if different from physical address): N/A

City: N/A — State: N/A — Zip: N/A

Telephone: 858-776-6010 — Website: http://www.tranzonic.com/

Licensing Company Email: justin.nunez@acutecareonline.com

Section 2: Personal Information

First: Justin — Middle: Michael — Last: Nunez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas — State: NV — Zip: [redacted]

Telephone: 858-776-6010 — Email: justin.nunez@acutecareonline.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palomar College		2016-2020	
Address	**City**	**State**	**Zip**
1140 W Msn	San Marcos	CA	92069
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Rancho Bernardo High School		2010-2014	
Address	**City**	**State**	**Zip**
13010 Paseo Lucido	San Diego	CA	92128
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2024-Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2023-2024		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
2017-2023		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
2014-2017		San Diego	CA	
From - To (MM/YY – MM/YY)		City	State	
1996-2014		San Deigo	CA	
From - To (MM/YY – MM/YY)		City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Acute Care Pharmaceuticals			2017-Present	
Business Address		**City**	**State**	**Zip**
12195 Dearborn Pl		San Diego	CA	92128
Phone	**Title**		**Number of Employed Hours**	
1-888-909-7700	Warehouse Lead		14,784 Hours	
Description of Duties				
Warehouse lead receiving and shipping inventory such as class medical devices. Assisted in curating crash cart kits under supervision of the DRIC. Arranging inventory in a FIFO format.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A		N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	V
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

10-31-24

Date

I, Justin Nunez, **certify that as the MDEG Administrator for**

The Tranzonic Companies,

that I (initial that you have read and meet the following requirements):

1. ____ Have a high school diploma or its equivalent;
2. ____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Just Nunez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10·31·24

Date

Board Use Only	Date Received: 11/5/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: The Tranzonic Companies

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 5850 E North Belt Rd

City: Las Vegas State: NV Zip: 89135

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 858-776-6010 Website: http://www.tranzonic.com/

Licensing Company Email: justin.nunez@acutecareonline.com

Section 2: Personal Information

First: Justin Middle: Michael Last: Nunez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITI[redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: 858-776-6010 Email: justin.nunez@acutecareonline.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palomar College		2016-2020	
Address	**City**	**State**	**Zip**
1140 W Msn	San Marcos	CA	92069
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Rancho Bernardo High School		2010-2014	
Address	**City**	**State**	**Zip**
13010 Paseo Lucido	San Diego	CA	92128
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2024-Current	[redacted]	Las Vegas	NV	[redacted]
2023-2024		San Diego	CA	
2017-2023		San Diego	CA	
2014-2017		San Diego	CA	
1996-2014		San Diego	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Acute Care Pharmaceutical			2017-Present	
Business Address		**City**	**State**	**Zip**
12195 Dearborn Pl.		San Diego	CA	92128
Phone	**Title**		**Number of Employed Hours**	
1-888-909-7700	Warehouse Lead		14,784	
Description of Duties				
Warehouse lead receiving and shipping inventory such as class medical devices. Assisted in curating crash cart kits under supervision of the DRIC. Arranging inventory in a FIFO format.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		City	State	Zip
N/A		N/A	N/A	N/A
Phone	Title		Number of Employed Hours	
N/A	N/A		N/A	
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

9-18-24

Date

I, Justin Michael Nunez, **certify that as the designated representative for**

The Tranzonic Companies,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JM I am at least 21 years of age;
3. JM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Justin Nunez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-23-24

Date

I, Justin Michael Nunez, **certify that as the designated representative for**

The Tranzonic Companies,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Justin Nunez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-18-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Nunez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-18-24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Justin Nunez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-18-24

Date

Subscribed and Sworn to before me this 18 day of Sept.

Notary Public Signature

Sherline Rodriguez
Notary Public - State of Nevada
County of Clark
Appt. No. 24-9920-01
My Appt. Expires: August 6, 2028

(Seal)

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Re: The Tranzonic Companies
Nevada Wholesaler Application

Employee List

Full Name	Job Title	Work Location
Agundez Yanez, Alex A.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Agundez, Gabriel	TNZ - Senior Lead	Tranzonic - Las Vegas
Agundez-yanez, Gabriel	TNZ - Department Lead	Tranzonic - Las Vegas
Aleman, Eduardo A.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Alexander, David	TNZ - Forklift Operator	Tranzonic - Las Vegas
Armendariz, Oscar	TNZ - Forklift Operator	Tranzonic - Las Vegas
Barsom, Amir	TNZ - Forklift Operator	Tranzonic - Las Vegas
Becerra, Jose D.	TNZ - Production Lead	Tranzonic - Las Vegas
Brooks, Taccara	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Brown, Drew	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Bruce, Doug	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Cain, Amanda M.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Felix, Alma P.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Felix, Kristal	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Fortez, Andre	TNZ - Forklift Operator	Tranzonic - Las Vegas
Fuller, Derick	TNZ - Forklift Operator	Tranzonic - Las Vegas
Gerges, Tamer	TNZ - Director, Distribution	Tranzonic - Las Vegas
Gonzalez Lopez, Gabino	TNZ - Warehouse Manager	Tranzonic - Las Vegas
Gonzalez, Monique S.	TNZ - Inventory Clerk	Tranzonic - Las Vegas
Hernandez, Raymond	TNZ - Forklift Operator	Tranzonic - Las Vegas
Hull, Patrick S.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Johnson, James C.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Jolly, Xavier	TNZ - Forklift Operator	Tranzonic - Las Vegas
Kedic, Amgad S.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Leafa, Mosooi U.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Licea, Rodrigo R.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Lockett, Steven R.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Lopez Escobar, Oscar	TNZ - Material Handler	Tranzonic - Las Vegas
Lopez, Salvador	TNZ - Forklift Operator	Tranzonic - Las Vegas
Lopez-Flores, Oscar	TNZ - Material Handler	Tranzonic - Las Vegas
Martin, Cordele A.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Monghur, Johnathan	TNZ - Forklift Operator	Tranzonic - Las Vegas
Noel, Joseph W.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Nunez, Justin M.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Nunez, William I.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Osorio, Sexangary	TNZ - Forklift Operator	Tranzonic - Las Vegas

Parker, Johnell	TNZ - Forklift Operator	Tranzonic - Las Vegas
Pen, Judy	TNZ - Forklift Operator	Tranzonic - Las Vegas
Reyes, Daniel	TNZ - Forklift Operator	Tranzonic - Las Vegas
Santos, Katherine Joyce D.	TNZ - Production Lead	Tranzonic - Las Vegas
Segundo, Arely A.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Segundo, Aylin L.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Shelby, Jamar J.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
TAWFIK, PETER	TNZ - Forklift Operator	Tranzonic - Las Vegas
Tela-Alapati, Tony L.	TNZ - Forklift Operator	Tranzonic - Las Vegas
Thomas, Teijuan A.	TNZ - Warehouse Associate	Tranzonic - Las Vegas
Webb, Clifton	TNZ - Forklift Operator	Tranzonic - Las Vegas
Wildey, Christian	TNZ - Forklift Operator	Tranzonic - Las Vegas
Winn, Antoine	TNZ - Forklift Operator	Tranzonic - Las Vegas
Zuniga, Ashly	TNZ - Warehouse Associate	Tranzonic - Las Vegas

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR NEVADA WAREHOUSE LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Warehouse ☑ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: WA 00004)

☐ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☑ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: Kuehne + Nagel Inc.

Physical Address: 2555 USA Parkway, #104

Mailing Address: 10 Exchange Place 20th Floor, Jersey City, NJ 07302

City: McCarran State: NV Zip Code: 89434

Telephone: 775-412-4070 Fax: N/A

Toll Free Number: N/A

E-mail: qshepharma.us@kuehne-nagel.com Website: https://us.kuehne-nagel.com/

Facility Manager: Sean Williams

Professional qualifications and experience of facility manager: Please see attached Resume

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☐ Manufacturer ☐ Chain Warehouse ☑ Wholesalers
☑ Other: Hospitals and Physicians

Type of Products to be handled or wholesaled be firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☑ Other: OTC drugs and devices
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR NEVADA WAREHOUSE LICENSE

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1)	Performance Health	9040 Orly Road, Suite 200, Indianapolis, IN 46242
	Name	Address
	Medical device supplier	
	Business	
2)	Sysco Guest Supply	300 Davidson Avenue, Somerset, NJ 08873
	Name	Address
	Housekeeping supplier	
	Business	
3)	FedEx Custom Critical	1475 Boettler Road, Uniontown, OH 44685
	Name	Address
	Shipping company	
	Business	
4)	Equinox Payments	8888 East Raintree Drive, Suite 300, Scottsdale, AZ 85260
	Name	Address
	Electronic Payment machines	
	Business	

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

APPLICATION FOR NEVADA WAREHOUSE LICENSE

This page must be submitted for all types of ownership.

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized warehouse may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Nadine Jones
Print Name of Authorized Person

Jun. 25, 2024.
Date

Board Use Only	Received: 12/11/24	Amount: $500 ck 1059

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: New York

Parent Company if any: Kuehne + Nagel Holdings Inc.

Corporation Name: Kuehne + Nagel Inc.

Mailing Address: 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 201-413-5500 Fax: N/A

Contact Person: Natalie Martino

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses.*

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

KUEHNE+NAGEL

Owner:
Kuehne + Nagel Holdings, Inc
10 Exchange Place 19th floor, Jersey City NJ 07302
FEIN: 81-5214188
100% Ownership

List of Officers:

Marcus Bennett, President/CEO

[redacted]

Dan Osterberg, CFO

[redacted]

Nadine Jones, Secretary

[redacted]

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	KUEHNE + NAGEL INC.
DOS ID Number:	200052
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/30/1966
Effective Date:	05/01/2023
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 16, 2024 at 04:29 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006589450 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"KUEHNE + NAGEL INVESTMENT LLC", A NEW JERSEY CORPORATION,

WITH AND INTO "KUEHNE + NAGEL HOLDINGS, INC." UNDER THE NAME OF "KUEHNE + NAGEL HOLDINGS, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE ON THE EIGHTEENTH DAY OF NOVEMBER, A.D. 2024, AT 4:03 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE FIRST DAY OF DECEMBER, A.D. 2024.

Jeffrey W. Bullock, Secretary of State

6271237 8100M
SR# 20244242053

Authentication: 204920760
Date: 11-20-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Storey County
Community Development
PO Box 526
Virginia City, NV 89440

Account #: 016775

2025

County of Storey

BUSINESS LICENSE

Date Issued: 7/01/2024
Class: GENERAL
Expires: 6/30/2025

This License is Granted to:

KUEHNE + NAGEL, INC.
KUEHNE + NAGEL, INC.
2555 USA PARKWAY
MCCARRAN NV 89434

KUEHNE + NAGEL, INC., having paid the required Storey County business license fee(s) in the amount of $ 650.00 is hereby granted permission to transact business under the GENERAL license for the period 7/01/2024 through 6/30/2025 in conformance with and subject to the County Commissioners of Storey County, Nevada.

~ COUNTERSIGNED ~

Jennifer McCain
Storey County Comptroller

Pete Renaud
Building Official

THIS LICENSE MUST BE DISPLAYED IN A CONSPICUOUS PLACE

****NON~TRANSFERABLE****

Phone (775)-847-0966 ~ Fax (775) 847-0935 ~ buslic@storeycounty.org

KUEHNE+NAGEL

Kuehne+Nagel U.S. Legal Structure

September 1, 2024

KUEHNE+NAGEL

Anticipated Kuehne+Nagel U.S. Legal Structure

December 1, 2024

KUEHNE+NAGEL

Kuehne + Nagel Inc.

10 Exchange Pl
Floor 20
Jersey City, NJ 07302

Tel.: +1 484.995.6137
ria.philip@kuehne-nagel.com

us.kuehne-nagel.com
www.kuehne-nagel.com

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:03 PM 11/18/2024
FILED 04:03 PM 11/18/2024
SR 20244242053 - File Number 6271237

STATE OF DELAWARE
CERTIFICATE OF MERGER OF
DOMESTIC CORPORATION AND
FOREIGN LIMITED LIABILITY COMPANY

Pursuant to Title 8, Section 264(c) of the Delaware General Corporation Law, the undersigned corporation executed the following Certificate of Merger:

FIRST: The name of the surviving corporation is KUEHNE + NAGEL HOLDINGS, INC., a Delaware Corporation, and the name of the limited liability company being merged into this surviving corporation is KUEHNE + NAGEL INVESTMENT LLC a *(list jurisdiction)* New Jersey limited liability company.

SECOND: The Agreement of Merger has been approved, adopted, certified, executed and acknowledged by the surviving corporation and the merging limited liability company.

THIRD: The name of the surviving corporation is Kuehne + Nagel Holdings, Inc.

FOURTH: The merger is to become effective on December 1, 2024.

FIFTH: The Agreement of Merger is on file at 10 Exchange Pl., 20th Fl. Jersey City, NJ 07302, the place of business of the surviving corporation.

SIXTH: A copy of the Agreement of Merger will be furnished by the corporation on request, without cost, to any stockholder of any constituent corporation or member of any constituent limited liability company.

SEVENTH: The Certificate of Incorporation of the surviving corporation shall be its Certificate of Incorporation.

IN WITNESS WHEREOF, said Corporation has caused this certificate to be signed by an authorized officer, the 11th day of November, A.D., 2024.

By: _____
Authorized Officer

Name: Nadine Jones
Print or Type

Title: Secretary

UNANIMOUS WRITTEN CONSENT

OF THE BOARD OF DIRECTORS OF

KUEHNE + NAGEL HOLDINGS, INC.

Pursuant to the authority contained in the provisions of Section 141(f) of the General Corporation Law of the State of Delaware, the undersigned, being all of the members of the board of directors (the "**Board**") of Kuehne + Nagel Holdings, Inc., a Delaware corporation (the "**Corporation**"), do hereby adopt the following resolutions with the same force and effect as though adopted at a meeting of the Board, and direct the Secretary of the Corporation to place a copy of this Written Consent in the minutes book of the Corporation:

WHEREAS, the Corporation is the sole member of Kuehne + Nagel Investment LLC, a New Jersey limited liability company ("**KNI LLC**").

WHEREAS, the Corporation has decided that KNI LLC should merge into and become part of the Corporation.

THEREFORE, IT IS

RESOLVED, that the Agreement and Plan of Merger by and among the Corporation and KNI LLC substantially in the form attached hereto, be approved;

RESOLVED, that KNI LLC shall merge into the Corporation under the terms set forth in the Agreement and Plan of Merger (the "Merger");

RESOLVED, that the officers of the Company are hereby authorized, empowered, and directed to execute the Agreement and Plan of Merger containing all of the material terms set forth in the form attached hereto, and to take any and all actions deemed by them to be necessary to effectuate the Merger and its terms;

RESOLVED, that this Unanimous Written Consent is being executed in lieu of a meeting of the board of directors of the Corporation and shall be filed with the minutes of proceedings of the directors of the Corporation.

RESOLVED, that this Written Consent may be in the form of an electronic record (in "*.pdf*" form or otherwise) and may be executed using electronic signatures, which shall be considered as originals and shall have the same legal effect, validity, and enforceability as a paper records.

[Signature page to follow]

IN WITNESS WHEREOF, the foregoing resolutions of the Board of Kuehne + Nagel Holdings, Inc. are hereby approved and adopted as of the date written below.

Marcus Bennett, Director

Nadine Jones, Director

Dan Osterberg, Director

Dated: November 11, 2024

EXHIBIT A

Agreement and Plan of Merger

See attached.

AGREEMENT
AND
PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER, dated as of November 11, 2024 (this "Plan of Merger"), is between Kuehne + Nagel Investment LLC, a New Jersey Limited Liability Company ("Merged LLC"), and Kuehne + Nagel Holdings, Inc., a Delaware corporation ("Surviving Corporation").

W I T N E S S E T H:

WHEREAS, Merged LLC has a single member to wit, the Surviving Corporation; and

WHEREAS, Surviving Corporation is authorized to issue a total of 100 shares of capital stock, consisting of 200 shares of common stock, par value $0.01 per share ("Surviving Corporation Common Stock"), of which, as of the date hereof, 100 shares of Common Stock are issued and outstanding; and

WHEREAS, the sole member and the Managers of the Merged LLC and the Board of Directors of the Surviving Corporation, respectively, approve and deem it advisable that Merged LLC and Surviving Corporation, respectively, consummate the Merger (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements contained in this Plan of Merger, the parties to this Plan of Merger hereby agree that Merged LLC shall be merged (the "Merger") with and into Surviving Corporation in accordance with applicable laws and upon the terms and subject to the conditions set forth as follows:

1. The Merger. At such time agreed between Merged LLC and Surviving Corporation, a certificate of merger evidencing the Merger shall be filed with each of the Office of the Secretary of State of the State of New Jersey pursuant to the Title 42 of the New Jersey Revised Statutes and of the State of Delaware General Corporation Law. The Certificates of Merger shall specify that the Merger shall become effective on December 1, 2024 ("Effective Time"). At the Effective Time, Merged LLC shall be merged with and into Surviving Corporation, and Surviving Corporation shall continue as the surviving corporation. The Surviving Corporation's name shall remain Kuehne + Nagel Holdings, Inc.

2. Certificate of Incorporation and By-laws. The Certificate of Incorporation and By-laws of Surviving Corporation in effect immediately prior to the Effective Time shall be and remain the Certificate of Incorporation and By-laws, respectively, of Surviving Corporation, as the surviving corporation, after the Effective Time, until amended as provided by law.

3. Officers and Directors. From and after the Effective Time, and until they shall have resigned or shall have been legally removed or until their respective successors shall have been elected or appointed and qualified, those persons who are the officers and directors of Surviving Corporation immediately prior to the Effective Time shall be the officers and directors of Surviving Corporation.

4. Effect of the Merger.

4.1 All assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC in and to every type of property (real, personal and mixed) and choses in action, as they exist as of the Effective Time, shall pass and be transferred to and vest in Surviving Corporation, as the surviving corporation, by virtue of the Merger at the Effective Time without any deed, conveyance or other transfer, and all such interests of Surviving Corporation as they exist as of the Effective Time shall remain with Surviving Corporation upon consummation of the Merger. The corporate existence of Surviving Corporation shall continue unaffected and unimpaired upon consummation of the Merger and the separate corporate existence of Merged LLC shall cease at and as of the Effective Time.

4.2 From and after the Effective Time, Surviving Corporation, as the surviving corporation, shall be responsible and liable for all of the liabilities and obligations of Surviving Corporation and Merged LLC existing as of the Effective Time. Any claim existing or action or proceeding pending by or against Surviving Corporation or Merged LLC at the Effective Time may, thereafter, be prosecuted by or against Surviving Corporation, as the surviving corporation, as if the Merger had not taken place or, in connection with any such action or proceeding to which Merged LLC is a party, Surviving Corporation, as the surviving corporation, may be substituted in place of Merged LLC. Neither the rights of creditors nor any liens upon the property of either Surviving Corporation or Merged LLC shall be impaired by reason of the Merger.

5. Effect of Merger on Outstanding Shares.

5.1 *Exchange Ratio*. At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof, all of the issued and outstanding member shares of the Merged LLC shall be cancelled.

5.2 *Closing of Transfer Books*. At the Effective Time, the membership transfer books of Merged LLC shall be closed and no transfer of shares of Merged LLC membership shall thereafter be made. If, after the Effective Time, certificates representing member shares of Merged LLC are presented to the Surviving Corporation, they shall be canceled in accordance with the terms hereof. At and after the Effective Time, the holders of member shares of Merged LLC Stock shall cease to have any rights as members of Merged LLC.

6. Further Assurances. From time to time after the Effective Time, as and when requested by Surviving Corporation, and to the extent permitted by law, the former managers of Merged LLC and the officers and directors of Surviving Corporation shall execute and deliver such assignments, deeds and other instruments and shall take or cause to be taken such further or other action as shall be necessary in order to consummate the Merger, vest or perfect in or to confirm of record or otherwise to Surviving Corporation, as the surviving corporation, title to, and possession of, all of the assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC and Surviving Corporation in and to every type of property (real, personal and

mixed) and choses in action, and otherwise to carry out the purposes of this Plan of Merger, and the proper officers and directors of Surviving Corporation, as the surviving corporation, are fully authorized to take any and all such action in the name of Merged LLC or Surviving Corporation or otherwise.

7. Termination and Amendment. Prior to the Effective Time, this Plan of Merger may be terminated or amended by the mutual consent of the Managers of Merged LLC and the Board of Directors of Surviving Corporation.

8. Counterparts. This Plan of Merger may be signed in any number of counterparts, each of which shall be deemed an original, and all of which shall be deemed but one and the same instrument.

9. Governing Law. This Plan of Merger shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New Jersey or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New Jersey.

IN WITNESS WHEREOF, the parties have duly executed this Plan of Merger as of the date first written above.

KUEHNE + NAGEL INVESTMENT LLC
(Merged LLC)

By: _____
Marcus Bennett, Manager

By: _____
Dan Osterberg, Manager

By: _____
Nadine Jones, Manager

KUEHNE + NAGEL HOLDINGS, INC.
(Surviving Corporation)

By: _____
Name: Dan Osterberg
Title: CFO, Treasurer

UMC-1 Rev. 3/2013

New Jersey Division of Revenue & Enterprise Services

Certificate of Merger/Consolidation

(Limited Liability Co.'s, Limited Partnerships & Partnerships)

To file electronically:
1. Enter the information requested below and sign by typing your name in the signature field. The form can only be filled in using the free Adobe Acrobat Reader 9.1 or greater. *(See the pages following this form for field by field instructions, and notes on delivery and processing of work requests.)*
2. Click the "Add Attachments" button to add attachments if required *(Check the field by field instructions to see if you must include an attachment(s)).*
3. After the form has been filled in properly, please save a copy to your computer so that you can upload the form to the State of New Jersey Division of Revenue & Enterprise Services Central Forms Repository Web application by following the instructions in the next step.
4. Click the "Open the Central Forms Repository Home Page to start the Form Submission Process" button at the bottom of the form.
(This action will launch the State of New Jersey Division of Revenue & Enterprise Services Central Forms Repository Web application. If you have not created an account in the application, you will need to do so before using the online Web application. Once your account is created, please login to the application *and follow the instructions for submitting your form and payment online.)*

This form may be used to record the merger or consolidation of a limited liability company, limited partnership or partnership with or into another business entity or entities, pursuant to NJSA 42. Applicants must insure strict compliance with the requirements of State law and insure that all filing requirements are met. This form is intended to simplify filing with the New Jersey State Treasurer. Applicants are advised to seek out private legal advice before submitting filings to the State Treasurer's office.

1. Type of Filing (check one): [X] Merger [ ] Consolidation
2. Name of Surviving Business Entity: KUEHNE+NAGEL HOLDINGS, INC.
3. Address of the Surviving Business Entity: 10 Exchange Pl, 20th Fl, Jersey City, NJ 07302
4. Name(s)/Jurisdiction(s) of All Participating Business Entities:

Name	Jurisdiction	Identification # Assigned by by Treasurer (if applicable)
Kuehne + Nagel Investment LLC	New Jersey	0100507656
Kuehne + Nagel Holdings, Inc.	Delaware	

5. Service of Process Address (For use if the surviving business entity is not authorized or registered by the State Treasurer):

c/o Kuehne + Nagel Inc.
10 Exchange Pl., 20th Fl. Jersey City, NJ 07302

The surviving business entity agrees that it may be served with process in this State in any action, suit or proceeding for the enforcement of any obligation of a merging or consolidating LLC, LP or partnership. The Treasurer is hereby appointed as agent to accept service of process in any such action, suit, or proceeding which shall be forwarded to the Surviving Business Entity at the Service of Process address stated above.

6. Effective Date (see instructions): December 1, 2024

The undersigned represent(s) that the agreement of merger/consolidation is on file at the place of business of the surviving business entity and that an agreement of merger/consolidation has been approved and executed by each business entity involved. Additionally, a copy of the merger/consolidation agreement has been or shall be furnished by the surviving entity to any member or any person having an interest.

The undersigned also represent(s) that they are authorized to sign on behalf of the surviving business entity.

Signature	Name	Title	Date
	Nadine Jones	Director	11/11/2024

**Important Notes --New Jersey law prohibits domestic LLCs, LPs and partnerships from merging/consolidating with another business entity, if authority for such merger/consolidation in not granted under the laws of the jurisdiction under which the other business entity was organized. Also, a merger/consolidation certificate may be filed pursuant to Title 42, 42:2A or 42:2B only if the surviving or resulting business entity is a limited partnership, limited liability company or partnership. Also, at least one participating business entity must be a limited partnership or limited liability company. If a for-profit domestic or foreign corporation participates or is the survivor, file the merger/consolidation pursuant to Title 14A. Title 15A corporations are not authorized to participate in mergers/consolidations involving LPs, LLCs, partnerships and for-profit corporations.

Employee List-RNO

First Name	Last Name	Status
Angel	Martinez	Active Employee
Candice	Conway	Active Employee
Cassie	Dobbins	Active Employee
Chris	Aleman	Active Employee
Chris	Wehr	Active Employee
Christie	Jones	Active Employee
Christine	Inga	Active Employee
Daniel	Olivera	Active Employee
David	Arevalo	Active Employee
David	Rodrigues	Active Employee
Estevon	Jacobs	Active Employee
Ferdinand	Agustin	Active Employee
Frankie	Rivera	Active Employee
Halsey	Thompson	Active Employee
James	Keppler	Active Employee
Jeremy	Holeman	Active Employee
Julie	Bressem	Active Employee
Katy	Ditmars	Active Employee
Malcolm	Millikin	Active Employee
Maria	Ramirez	Active Employee
Maury	Melara	Active Employee
Monte	Tackman	Active Employee
Morgan	Norris	Active Employee
Nate	Hanson	Active Employee
Noah	Svenningsen	Active Employee
Osvel	Cisneros	Active Employee
Perla	Rivera	Active Employee
Reese	Hamilton	Active Employee
Rhiannon	Melville	Active Employee
Robert	Hennings	Active Employee
Sean	Williams	Active Employee
Sunni	Leggate	Active Employee
Troy	Voldseth	Active Employee

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kuehne + Nagel Inc.

Pharmacy/Wholesaler License # (if applicable) WA00004

Physical Address 2555 USA Parkway, Suite 104

City McCarran State NV Zip 89434

Mailing Address (if different from physical address) 10 Exchange Place, 19th Floor

City Jersey City State NJ Zip 07302

Telephone 775-412-4070 Website https://us.kuehne-nagel.com/en/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Sean Middle Matthew Last Williams

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City Sparks State N V Zip [redacted]

Telephone [redacted] Email sean.williams@kuehne-nagel.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		02/1997 to 06/2000	
Address	City	State	Zip
3590 N First Street	San Jose	CA	95134
Diploma/Degree obtained, if any			
BS Business Management			

School Name		From - To (MM/YY – MM/YY)	
Sierra Academy of Aeronautics		02/1989 to 05/1990	
Address	City	State	Zip
2305 Jetleft Drive	Atwater	CA	95301
Diploma/Degree obtained, if any			
FFA Airframe & Powerplant license			

School Name		From - To (MM/YY – MM/YY)	
Woodland Park High School		08/1983 to 05/1987	
Address	City	State	Zip
151 Panther Way	Woodland Park	CO	80863
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2000 to present	[redacted]	Sparks	NV	[redacted]
03/1999 to 09/2000		Newark	CA	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/4/25
Date

I, Sean Williams, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SMW I am at least 21 years of age;
3. SMW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SMW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SMW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SMW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SMW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sean Williams
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/4/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean Williams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/5/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of WASHOE

I, Sean Williams, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/5/2025

Date

Subscribed and Sworn to before me this 5TH day of FEB.

Notary Public Signature

KEVIN ORR
Notary Public, State of Nevada
Appointment No. 24-7025-02
My Appt. Expires Sep 13, 2028

(Seal)

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AMG Pharmacy

Physical Address: 4655 Quality Ct., STE D

City: Las Vegas State: NV Zip: 89103

Mailing Address (if different from physical address): 7958 Cape Flattery Ave

City: Las Vegas State: NV Zip: 89147

Telephone: (949) 228 - 8389 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: APRILT@AMGPHARMACY.COM

Website: _____

Nevada Business License # (if applicable) NV20253294570

Supervising/Managing Pharmacist Name (NRS 639.220): Terry Kang

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19426

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Terry Kang	NV Pharmacist Registration #: 19426
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: April M. Tsai	Credentials: PT29164	%: 100
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: April M. Tsai

Business Name: April MT LLC

Business Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER (title) for AMG PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

April M. Tsai

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2 / 28 / 2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, April M. Tsai hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for AMG PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28 day of Feb, 20 25

Notary Public

WEIZHEN WANG
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 18-3960-1
MY APPT. EXPIRES SEPT. 9, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Terry Kang Pharmacist Registration #: 19426

Pharmacy Name: AMG Pharmacy

Initial each statement below to indicate you have read and agree with the following:

TK I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

TK I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

TK I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

TK I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

TK I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Terry Jake Kang
Original signature of Managing Pharmacist (copies or stamps not accepted)

2-27-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

April M. Tsai

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2 / 28 / 2025

Date

Board Use Only	Date Received: 3/4/25	Amount: $500 CK 1004

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **AMG Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/18/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/27/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502275478299
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AMG Pharmacy
Pharmacy/Wholesaler License # (if applicable) _____
Physical Address 4655 Quality Ct., STE D
City Las Vegas State NV Zip 89103
Mailing Address (if different from physical address) 7958 Cape Flattery Ave
City Las Vegas State NV Zip 89147
Telephone (949) 228 - 8389 Website _____
Licensing Company Email aprilt@amgpharmacy.com

Section 2: Personal Information

First April Middle M. Last Tsai
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X
Mailing Address [redacted]
City Las Vegas State NV Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rancho High School Magnet Program		08/2002 - 06/2006	
Address	**City**	**State**	**Zip**
1900 Searles Ave	Las Vegas	NV	89101
Diploma/Degree obtained, if any			
High school Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		08/2006 - 06/2014	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
Bachelor in Psychology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2012 - Current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/2015 - 07/2021		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
LV Pharmacy and Medical Supplies			10/2023 -	
Business Address		**City**	**State**	**Zip**
4503 W. Sahara Ave STE 170		Las Vegas	NV	89102
Phone	**Title**		**Number of Employed Hours**	
(702) 866 - 7777	Pharmacy Technician Auditor		3,114 Hours	
Description of Duties				
Compliance officer - Make sure adjudicated claims to the insurance are billed correctly and notated, Human Resource - Employee SOP is created, Administration - accreditation are all updated, Biller/Filler - process and filled claims.				

Business Name			From - To (MM/YY – MM/YY)	
Aeva Specialty Pharmacy			02/2020 - 11/2023	
Business Address		**City**	**State**	**Zip**
6280 S Valley View Ste 732		Las Vegas	NV	89118
Phone	**Title**		**Number of Employed Hours**	
(702) 558 - 2382	Pharmacy Facility Manager and Developer		6,066 Hours	
Description of Duties				
Managed the Pharmacy and Durable Medical Equipment ensuring the process are completed by start to finish. Ensure the Pharmacy Software and Durable Medical Equipment software is running correctly and efficiently with formatting.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, April M. Tsai, **certify that as the designated representative for**

AMG Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AT I am at least 21 years of age;
3. AT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

April M. Tsai

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/28/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

April M. Tsai

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/28/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of clark

I, APRIL M. TSAI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/28/2025

Date

Subscribed and Sworn to before me this 28 day of Feb. 2025

Notary Public Signature

WEIZHEN WANG
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 18-3960-1
MY APPT. EXPIRES SEPT. 9, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AMG Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 4655 Quality Ct. STE D

City Las Vegas State NV Zip 89103

Mailing Address (if different from physical address) 7958 Cape Flattery Ave.

City Las Vegas State NV Zip 89147

Telephone (949) 228 - 8389 Website _____

Licensing Company Email APRILT@AMGPHARMACY.COM

Section 2: Personal Information

First April Middle M. Last Tsai

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rancho High School Magnet Program		08/2002 - 06/2006	
Address	**City**	**State**	**Zip**
1900 Searles Ave	Las Vegas	NV	89101
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		08/2006 - 06/2014	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2012 - Current	[redacted]	Las Vegas	NV	[redacted]
06/2015 - 07/2021		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
LV Pharmacy and Medical Supplies			10/2023 -
Business Address	**City**	**State**	**Zip**
4503 S. Sahara Ave Ste 170	Las Vegas	NV	89102
Phone	**Title**		
702 - 866 - 7777	Pharmacy Technician Auditor		

Description of Duties

Compliance officer - Make sure adjudicated claims to the insurance are billed correctly and notated, Human Resource - Employee SOP is created, Administration - accreditation are all updated, Biller/Filler - process and filled claims.

Business Name			From - To (MM/YY – MM/YY)
Aeva Specialty Pharmacy			02/2020 - 11/2023
Business Address	**City**	**State**	**Zip**
6280 S Valley View Ste 732	Las Vegas	NV	89118
Phone	**Title**		
(702) 558 - 2382	Pharmacy Facility Manager and Developer		

Description of Duties

Managed the Pharmacy and Durable Medical Equipment ensuring the process are completed by start to finish. Ensure the Pharmacy Software and Durable Medical Equipment software is running correctly and efficiently with formatting.

Business Name			From - To (MM/YY – MM/YY)
MGM Grand Hotel and Casino			08/2008 - 01/2020
Business Address	**City**	**State**	**Zip**
3799 S Las Vegas Blvd	Las Vegas	NV	89109
Phone	**Title**		
(877) 880-0880	Guest Services - Front Desk		

Description of Duties

Axillary Position: Internal Audit. Ensure the check in and check out process status are complete. Run all report for night audit to confirm the third party billing and groups contract are correct.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

April M. Tsai

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 2/28/2025

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, APRIL M. TSAI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 2/28/2025

Subscribed and Sworn to before me this 28 day of Feb. 2025

Notary Public Signature

WEIZHEN WANG
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 18-3960-1
MY APPT. EXPIRES SEPT. 9, 2026

(Seal)

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FF4966644
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 04395		☑ Other: Delivery (Local)

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: First Choice Pharmacy, LLC

Physical Address: 7260 S. Cimarron Rd Ste 115

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 444-4210 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: (877) 593-8345 Contact Email: 7260pharmacy@gmail.com

Website: _____

Nevada Business License # (if applicable) NV20212141719

Supervising/Managing Pharmacist Name (NRS 639.220): Kirk J Beaulieu

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20184

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kirk J Beaulieu	NV Pharmacist Registration #: 20184
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b). Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: First Choice Pharmacy, LLC

Mailing Address: 7260 S. Cimarron Rd Suite 115

City: Las Vegas State: NV Zip: 89113

Telephone: (702) 444-4210 Email: 7260pharmacy@gmail.com

Contact Person Name: Kirk Beaulieu

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager/Pharmacist-in-Charge (title) for First Choice Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Kirk J Beaulieu

Print Name of Authorized Person

Kirk J Beaulieu

Original signature of Authorized Person (copies or stamps not accepted)

1/28/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Kirk J Beaulieu hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager/Pharmacist in charge (title) for First Choice Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Kirk J Beaulieu
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28th day of January, 2025

Notary Public

NOTARY PUBLIC
JOSE I. ESCALONA
STATE OF NEVADA - COUNTY OF CLARK
MY APPOINTMENT EXP. APRIL 18, 2027
No: 94-4123-1

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Kirk J Beaulieu Pharmacist Registration #: 20184

Pharmacy Name: First Choice Pharmacy, LLC

Initial each statement below to indicate you have read and agree with the following:

KB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

KB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

KB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

KB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

KB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirk J Beaulieu
Original signature of Managing Pharmacist (copies or stamps not accepted)

1/28/2005
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirk J Beaulieu

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kirk J Beaulieu

Original signature of Authorized Person (copies or stamps not accepted)

1/28/2025

Date

Board Use Only	Date Received: 3/7/25	Amount: $500 CK 1160

First Choice Pharmacy Owners and Officers

Kirk Beaulieu	100% Owner/Manager/Pharmacist in Change

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **First Choice Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/18/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/07/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502075424339
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site First Choice Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7260 S. Cimarron Rd

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 444-4210 Website _____

Licensing Company Email 7260pharmacy@gmail.com

Section 2: Personal Information

First Kick Middle J Last Beaulieu

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] N or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addr[redacted]

City Las Vegas State NV Z[redacted]

Telephon[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Massachusetts College of Pharmacy and Allied Health Sciences	08/86 – 12/90

Address	City	State	Zip
179 Longwood Ave	Boston	MA	02115

Diploma/Degree obtained, if any: B.S. Pharmacy

School Name	From - To (MM/YY – MM/YY)
Washburn District High School	08/82 – 06/86

Address	City	State	Zip
1359 Main St	Washburn	ME	04786

Diploma/Degree obtained, if any: College Preparatory Diploma

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/23 — Present	[redacted]	Las Vegas	NV	[redacted]
11/21 — 12/22	[redacted]	Las Vegas	NV	
07/04 — 10/21	[redacted]	Hermon	ME	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
First Choice Pharmacy, LLC			11/23 – Present	
Business Address	**City**		**State**	**Zip**
7260 S. Cimarron Rd	Las Vegas		NV	89113
Phone	**Title**			
(702) 444-4210	Pharmacist-In-Charge/ Manager			
Description of Duties				
- All duties of a Pharmacist And technician, Counseling, Inventory Control - Make all decisions in regards to the operation of the Pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			12/21 – 9/23	
Business Address	**City**		**State**	**Zip**
1101 S. Las Vegas Blvd	Las Vegas		NV	89104
Phone	**Title**			
closed	Pharmacist-In-Charge			
Description of Duties				
- All dutres of a pharmacist, Inventory Control, Scheduling, Budgeting - Patient Customer Service				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			05/2010 – 11/2021	
Business Address	**City**		**State**	**Zip**
706 Broadway	Bangor		ME	04401
Phone	**Title**			
(207) 262-0190	Pharmacist-In-Charge			
Description of Duties				
- All duties of a Pharmacist, Inventory Control, Scheduling, Budgeting customer service, patient care				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kirk Beaulieu

Print Name (First, Last)

Kirk J Beaulieu — 1/28/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Kirk Beaulieu, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kirk J Beaulieu — 2/25/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 25th day of February, 2025

J. Liaos

Notary Public Signature

JIM LIAOS
Notary Public
State of Nevada
Appt. No. 07-1102-1
My Appt. Expires December 30, 2026

(Seal)

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #:		☐ Other:
	PH_____		

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☑ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: HEALTHY CHOICE PHARMACY

Physical Address: 1850 E. SERENE AVENUE UNIT 107

City: LAS VEGAS State: NV Zip: 89123

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 750-9955 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: (702) 754-0445 Contact Email: HEALTHYCHOICEPHARMACYNV@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) NV20253291680

Supervising/Managing Pharmacist Name (NRS 639.220): OLIVE BAYLE

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19515

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: OLIVE BAYLE	NV Pharmacist Registration #: 19515
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: HEALTHY CHOICE PHARMACY LLC

Mailing Address: 1650 E. SERENE AVENUE UNIT 107

City: LAS VEGAS State: NV Zip: 89123

Telephone: (702) 738-7375 Email: HEALTHYCHOICEPHARMACYNV@GMAIL.COM

Contact Person Name: BRANDON ALLEN B. CATACUTAN

Please check type of partnership (NAC 639.214) ☐ General ☑ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER (title) for HEALTHY CHOICE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

BRANDON ALLEN B. CATALUTAN

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

02/12/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, BRANDON ALLEN B. CATACUTAN hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for HEALTHY CHOICE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18th day of February, 2025

Mandip Kaur
Notary Public

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
February 20, 2027
No. 23-7466-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: OLIVE BAYLE Pharmacist Registration #: 19JIT

Pharmacy Name: Healthy Choice Pharmacy

Initial each statement below to indicate you have read and agree with the following:

OB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

OB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

OB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

OB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

OB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

OBayle
Original signature of Managing Pharmacist (copies or stamps not accepted)

February 12, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRANDON ALLEN B. CATALUTAN

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

02/12/2025

Date

Board Use Only	Date Received: 2/24/25	Amount: $500.00

List of the Names of Limited Partners of Healthy Choice Pharmacy

Brandon Allen B. Catacutan: 50% Ownership

Giovanni P. Bayle: 50% Ownership

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Healthy Choice Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/11/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/12/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502125434581
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HEALTHY CHOICE PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1850 E. Serene Ave, Unit 107

City Las Vegas State NV Zip 89123

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 750-9955 Website _____

Licensing Company Email HEALTHY CHOICE PHARMACYNV@GMAIL.COM

Section 2: Personal Information

First OLIVE Middle ACEDERA Last BAYLE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres[redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF SANTO TOMAS			06/1990 - 3/1994	
Address	**City**	**State**	**Zip**	
España Blvd, Sampaloc	Manila City	Philippines		
Diploma/Degree obtained, If any				
B.S. Pharmacy				

School Name			From - To (MM/YY – MM/YY)	
DIVINE WORD COLLEGE OF CALAPAN - High School Department			06/1986 - 03/90	
Address	**City**	**State**	**Zip**	
Calapan Oriental Mindoro	Calapan City	Philippines		
Diploma/Degree obtained, If any				
High School graduate				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, If any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, If any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, If any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2019 - present	[redacted]	Las Vegas	NV	[redacted]
8/2018 - 8/2019		Las Vegas	NV	
3/2014 - 8/2018		Shorewood	WI	
9-2019 - 3/20N		Shorewood	WI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: CVS Pharmacy 5043			From - To (MM/YY – MM/YY): 5/2023 - present
Business Address: 9695 S. Maryland Pkway	City: Las Vegas	State: NV	Zip: 89123
Phone: 702- 896 - 1283	Title: District support Pharmacist		Number of Employed Hours: 3360 hours
Description of Duties: verify dosage prescribed by health care providers ; counsels patients on use of drugs , side effects ; consults with patients or medical practitioners on drug indication , contraindication , side effects.			
Business Name: CVS Pharmacy 5942			From - To (MM/YY – MM/YY): 10/2021 to - 4/2023
Business Address: 7285 S. Durango Dr	City: Las Vegas	State: NV	Zip: 89113
Phone: 702- 407 - 2933	Title: Pharmacy Manager / District Support RPh		Number of Employed Hours: 2880 hours
Description of Duties: Oversees the operational performance of the pharmacy. Dispenses the correct medication ordered by health care professional's. Counsels patients on use, side effects, contraindication of drugs			
Business Name: CVS Pharmacy 7251			From - To (MM/YY – MM/YY): 3/2021 - 9/2021
Business Address: 7285 N. Alliante Pkway	City: North Las Vegas	State: NV	Zip: 89084
Phone: 702- 642 - 0641	Title: District Support Pharmacist		Number of Employed Hours: 1080 hours
Description of Duties: Review orders of healthcare professionals ; dispenses the correct medication ordered by health care providers. ; counsel patients on use , contraindication , side effects of drug.			
Business Name: CVS Pharmacy 5144			From - To (MM/YY – MM/YY): 8/2018 - 2/2021
Business Address: 1425 W. Lake Mead Blvd	City: Las Vegas	State: NV	Zip: 89106
Phone: 702- 638 -1685	Title: Pharmacy Manager		Number of Employed Hours: 4800 hours
Description of Duties: Manages the overall performance of the pharmacy. ; dispense the correct medications , counsels patients on use , side effects, contraindication of drugs.			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, OLIVE BAYLE, **certify that as the designated representative for**

HEALTHY CHOICE PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. OB I am at least 21 years of age;
3. OB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. OB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. OB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. OB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. OB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

OLIVE BAYLE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 18. 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

OLIVE BAYLE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-18-2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of Clark

I, OLIVE BAYLE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02-18-2025

Date

Subscribed and Sworn to before me this 18 day of February.

Notary Public Signature

TROY ALLEN
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-19-28
Certificate No: 24-1455-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site HEALTHY CHOICE PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1850 E. SERENE AVENUE UNIT 107

City LAS VEGAS State NV Zip 89123

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 750-9955 Website _____

Licensing Company Email HEALTHY CHOICE PHARMACY NV @ GMAIL. COM

Section 2: Personal Information

First BRANDON ALLEN Middle BLAS Last CATACUTAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
CENTRO ESCOLAR UNIVERSITY MAKATI		08/23 – 05/24	
Address	**City**	**State**	**Zip**
259 SEN. GIL J. PUYAT AVE	MAKATI	METRO MANILA	1203
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE SPECIALIZED IN CLINICAL PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
CENTRO ESCOLAR UNIVERSITY MAKATI		08/19 – 05/23	
Address	**City**	**State**	**Zip**
259 SEN. GIL J. PUYAT AVE	MAKATI	METRO MANILA	1203
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE IN PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
SILVERADO CAREER AND TECHNICAL HIGH SCHOOL		08/15 – 05/19	
Address	**City**	**State**	**Zip**
1650 SILVER HAWK AVE	LAS VEGAS	NV	89123
Diploma/Degree obtained, if any			
ADVANCED HONORS DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06 – RECENT	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: CVS			From - To (MM/YY – MM/YY): 11/24 - RECENT
Business Address: 9695 S. MARYLAND PKWY	City: LAS VEGAS	State: NV	Zip: 89123
Phone: (702) 896-1283	Title: PHARMACY TECHNICIAN		
Description of Duties: TYPING, FILLING, CASHIER, DROP-OFF			

Business Name: WALGREENS			From - To (MM/YY – MM/YY): 03/22 - 01/23
Business Address: 9305 S. EASTERN AVE	City: LAS VEGAS	State: NV	Zip: 89123
Phone: (702) 914-9797	Title: PHARMACY TECHNICIAN		
Description of Duties: TYPING, FILLING, CASHIER, DROP-OFF, COVID-TESTING			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRANDON ALLEN, CATACUTAN
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/12/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of clark

I, BRANDON ALLEN B. CATACUTAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/18/2025
Date

Subscribed and Sworn to before me this 18th day of February, 2025

Mandip Kaur
Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
February 20, 2027
No. 23-7466-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site HEALTHY CHOICE PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1850 E. SERENE Avenue, Unit 107

City Las Vegas State NV Zip 89123

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 750-9955 Website _____

Licensing Company Email HEALTHYCHOICEPHARMACYNV@GMAIL.COM

Section 2: Personal Information

First GIOVANNI Middle PASCUAL Last BAYLE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☑ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
EMILIO AGUINALDO COLLEGE			6/1995 - 3/2002	
Address	**City**	**State**	**Zip**	
1113 San Marcelino St, Paco	Manila City	Philippines		
Diploma/Degree obtained, if any				
BS. Respiratory Therapy				

School Name			From - To (MM/YY – MM/YY)	
QUIAPO PAROCHIAL HIGH SCHOOL			6/85 - 3/89	
Address	**City**	**State**	**Zip**	
1053 E. Hidalgo St, Quiapo	Manila City	Philippines		
Diploma/Degree obtained, if any				
graduate				

School Name			From - To (MM/YY – MM/YY)	
G.M				
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2019 - present	[redacted]	Las Vegas	NV	[redacted]
8/2018 - 8/2019		Las Vegas	NV	
3/2014 - 8/2018		Shorewood	WI	
9/2009 - 3/2014		Shorewood	WI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
UBER			5/2021 - present	
Business Address	**City**	**State**	**Zip**	
5031 Wagon Trail Ave, Ste 111	Las Vegas	NV	89118	
Phone	**Title**			
800- 593-7069	Uber driver			
Description of Duties				
Responsible for picking-up and driving customers to their destination				

Business Name			From - To (MM/YY – MM/YY)	
FINDLAY CHEVROLET				
Business Address	**City**	**State**	**Zip**	
6800 S. Torrey Pines Dr	Las Vegas	NV	89118	
Phone	**Title**			
702- 982- 4000	automotive technician			
Description of Duties				
Perform basic care and maintenance of vehicle; Repair and replace worn parts. Explain automotive problems and repairs to clients				

Business Name			From - To (MM/YY – MM/YY)	
QUICK LANE and TIRE AUTO CENTER			7/2015 - 8/2018	
Business Address	**City**	**State**	**Zip**	
7800 N. 76th St	Milwaukee	WI	53223	
Phone	**Title**			
414- 3455261	automotive technician			
Description of Duties				
Perform basic care and maintenance of cars; Repairs and replaces worn parts. Explain automotive problems and repairs to clients				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

GIOVANNI BAYLE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-18-2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of Clark

I, GIOVANNI BAYLE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02-18-2025

Date

Subscribed and Sworn to before me this 18 day of febuary

Notary Public Signature

TROY ALLEN
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-13-28
Certificate No: 24-1455-01

(Seal)

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FB5538458
	☑ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 03433		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

Physical Address: 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Telephone: 702-754-0172 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Sean M. Barclay

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 17303

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sean M. Barclay	NV Pharmacist Registration #: 17303
Name: *please see attached*	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): OGB Meta III, LLC

Corporation/Organization Name: Meta Pharmacy Services, LLC

Mailing Address: 1015 Atlantic Blvd, STE 433

City: Atlantic Beach State: FL Zip: 32233

Telephone: (917) 288-7585 Email: derek@jbncp.com

Contact Person Name: Derek O'Leary

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President and Secretary (title) for Meta Pharmacy Services (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Sean M. Barclay

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/24/2024

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Sean M. Barclay Pharmacist Registration #: 17303

Pharmacy Name: Meta Pharmacy Services

Initial each statement below to indicate you have read and agree with the following:

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Operating a pharmacy without a license	Nevada	04/10/2019	19-002-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

Date 12/24/2024

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean M. Barclay, Vice President and Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/24/2024
Date

Board Use Only	Date Received: 12/30/24	Amount: $500.00

Nevada State Board of Pharmacy, Case Numbers: 19-002-RPH-S and 19-002-PH-S

On April 10, 2019 the Nevada State Board of Pharmacy ("Board of Pharmacy") finalized a Findings of Fact, Conclusions of Law and Order ("Order) between the Board of Pharmacy, pharmacist Mr. Sean Barclay and Meta Pharmacy Services, LLC dba Meta Pharmacy Services, (formerly known as Barclay Luke & Pillai Specialty Pharmacy PLLC dba Meta Pharmacy Services) located at 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Nevada Resident Pharmacy Permit #: PH03433).

On or about November 27, 2018, the Board of Pharmacy alleged that Mr. Barclay, acting as a licensed Nevada pharmacist and as the managing pharmacist for Meta Pharmacy Services, had operated a pharmacy from approximately November 1, 2017 to November 29, 2018, in the state of Nevada, without a current license or registration with the Board of Pharmacy.

Mr. Barclay and Meta Pharmacy Services did not oppose the citation. Mr. Barclay agreed to pay the $3,500 personal fine and Meta Pharmacy Services agreed to pay the $7,683.99 facility fine issued by the Board of Pharmacy.

Upon receipt of the fines, and signed Order, the Board of Pharmacy considered the matter closed and took no further action.

FILED
APR 26 2019
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NOS. 19-002-RPH-S**
	)	**19-002-PH-S**
Petitioner,	)	
v.	)	
	)	
SEAN BARCLAY, R.PH.,	)	**FINDINGS OF FACT,**
Certificate of Registration No. 17303,	)	**CONCLUSIONS OF LAW**
	)	**AND ORDER**
and	)	
	)	
META PHARMACY SERVICES,	)	
Certificate of Registration No. PH03433	)	
	)	
Respondents. /		

The Nevada State Board of Pharmacy (Board) heard this matter at its regularly scheduled meeting on April 10, 2019, in Las Vegas, Nevada. S. Paul Edwards, Esq., prosecuted the case on behalf of the State of Nevada, Board of Pharmacy. Sean Barclay, R.Ph., Certificate of Registration No. 17303 (Barclay), appeared in his capacity as the managing pharmacist/pharmacist in charge of Respondent Meta Pharmacy Services, Certificate of Registration No. PH03433 (Meta Pharmacy). He also appeared in his capacity as Meta Pharmacy's authorized representative. Neither Respondent had counsel, and neither Respondent disputed the allegations set forth in the Accusation on file herein.

Based on the evidence presented, including testimony from Barclay, the Board hereby enters the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. On or about November 27, 2018, Board Staff and the Food and Drug Administration (FDA) conducted a joint inspection of Meta Pharmacy.

2. During that inspection, Board Staff discovered that Barclay's Nevada pharmacist registration, Certificate of Registration No. 17303, expired on October 31, 2017, and that Barclay did not hold a current pharmacist registration.

3. Board Staff obtained Barclay's work schedule from November 2017, through November 2018, from Meta Pharmacy.

4. From the records Meta Pharmacy provided, Board Staff ascertained that Barclay had worked at Meta Pharmacy approximately two-hundred and twenty-four (224) days from November 1, 2017, through November 29, 2018, without a license or registration with the Board.

5. Barclay's work history also revealed that he was employed as Meta Pharmacy's managing pharmacist/pharmacist in charge during the time period that his pharmacist registration was expired.

6. On the days that Barclay worked without a current pharmacist registration, Meta Pharmacy operated without a registered managing pharmacist, and with an unregistered person on site (Barclay) who was engaged in the practice of pharmacy.

7. On November 29, 2018, Board Staff served Barclay with a Cease and Desist Order and Citation for the Unregistered Practice of Pharmacy.

8. On January 11, 2019, Board Staff served Barclay with a Citation for the Unregistered Practice of Pharmacy and fined him $5,000.00 for working approximately two-hundred and twenty-four (224) days without a current pharmacist registration.

9. Barclay did not seek a hearing to oppose that citation.

10. Board Staff incurred costs and expenses of three thousand six hundred eighty-three dollars ($3,683.99) to partially reimburse the Board for costs associated with investigating and prosecuting this matter.

CONCLUSIONS OF LAW

11. As the pharmacist in charge of a pharmacy that operated with an unregistered person on site who engaged in the practice of pharmacy, Barclay violated Nevada Revised

Statute (NRS) 639.220(1) and NRS 639.284(2), as well as Nevada Administrative Code (NAC) 639.945(1)(i) and (j), which violations are grounds for discipline pursuant to NRS 639.210(4), (11), (12) and/or (15) and NAC 639.702, as well as NRS 639.255 and NAC 639.955.

12. As the owner and operator of the pharmacy in which Barclay violated Nevada law, as indicated above, including in the First Cause of Action, Meta Pharmacy is responsible for those violations pursuant to NAC 639.945(2), which is grounds for discipline pursuant to NRS 639.210(11) and (12), NRS 639.230(5), NRS 639.255 and NAC 639.955.

13. In owning and operating a pharmacy without a registered pharmacist acting as the pharmacist in charge, Meta Pharmacy Services violated NRS 639.220(1) and NRS 639.284(1), which violations are grounds for discipline pursuant to NRS 639.210(4), (11) and (12), NRS 639.255 and NAC 639.955.

14. The costs and attorney fees Board Staff incurred to investigate and prosecute this case are fair and reasonable, necessary and actually incurred by Board Staff in its investigation and prosecution of this case.

ORDER

15. Based upon the foregoing, the BOARD HEREBY ORDERS:

a. Barclay shall pay a fine of two thousand five hundred dollars ($2,500.00).

b. Barclay shall pay an administrative fee of one thousand dollars ($1,000.00) to partially reimburse the Board for its costs and expenses associated with investigating and prosecuting this matter.

c. Meta Pharmacy shall pay a fine of five thousand dollars ($5,000.00).

d. Meta Pharmacy shall pay an administrative fee of two thousand six hundred eighty-three dollars ($2,683.99) to partially reimburse the Board for its costs and expenses associated with investigating and prosecuting this matter.

16. Respondents shall pay the fines ordered herein by *cashier's check* or *certified check* or *money order* made payable to "*State of Nevada, Office of the Treasurer*" to be received

by the Board's Reno office at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521, within sixty (60) days of the effective date of this Order.

17. Respondents shall pay the administrative fees ordered herein by *cashier's check* or *certified check* or *money order* made payable to the "*Nevada State Board of Pharmacy*" to be received by the Board's Reno office at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521, within sixty (60) days of the effective date of this Order.

18. Board Staff has authority to offer to Respondents, and each of them, a plan by which they can pay the fines and administrative fees ordered herein through installments which may exceed the sixty-day time limit ordered above. The terms of such a payment plan shall be at Board Staff's sole judgment and discretion.

19. Any failure by Respondents, or either of them, to comply with any term in this Order may result in additional discipline, including the possible suspension or revocation of their respective license or registration until the default is cured. Furthermore, any failure to pay any fine, fee, or cost ordered herein will also result in such legal action as Board Staff determines to be necessary to collect the unpaid fine, fee, or cost.

IT IS SO ORDERED.

Signed and effective this 26 day of April 2019.

Jason Penrod, President
Nevada State Board of Pharmacy

FILED
MAR 0 8 2019
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NOS. 19-002-RPH-S**
	)	**19-002-PH-S**
Petitioner,	)	
v.	)	
	)	
SEAN BARCLAY, R.PH.,	)	**NOTICE OF INTENDED ACTION**
Certificate of Registration No. 17303,	)	**AND ACCUSATION**
	)	
and	)	
	)	
META PHARMACY SERVICES,	)	
Certificate of Registration No. PH03433	)	
	)	
Respondents.	/	

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Sean Barclay, Certificate of Registration No.17303 (Barclay), was a registered pharmacist with the Board, and Respondent Meta Pharmacy Services. Certificate of Registration No. PH03433 (Meta Pharmacy), was a pharmacy registered with the Board.

II.

On or about November 27, 2018, Board Staff and the Food and Drug Administration (FDA) conducted a joint inspection of Meta Pharmacy.

III.

During that inspection, Board Staff discovered that Barclay's Nevada pharmacist registration, Certificate of Registration No. 17303, expired on October 31, 2017, and that Barclay did not hold a current pharmacist registration.

IV.

Board Staff obtained Barclay's work schedule from November 2017, through November 2018, from Meta Pharmacy.

V.

From the records Meta Pharmacy provided, Board Staff ascertained that Barclay had worked at Meta Pharmacy approximately two-hundred and twenty-four (224) days from November 1, 2017, through November 29, 2018, without a license or registration with the Board.

VI.

Barclay's work history also revealed that he was employed as the managing pharmacist of Meta Pharmacy during the time period that his pharmacist registration was expired.

VII.

On the days that Barclay worked without a current pharmacist registration, Meta Pharmacy operated without a managing pharmacist who was registered with the Board and without a registered staff pharmacist on site.

VIII.

On November 29, 2018, Board Staff served Barclay with a Cease and Desist Order and Citation for the Unregistered Practice of Pharmacy.

IX.

On January 11, 2019, Board Staff served Barclay with a Citation for the Unregistered Practice of Pharmacy and fined him $5,000.00 for working approximately two-hundred and twenty-four (224) days without a current pharmacist registration. Barclay did not seek a hearing to oppose that citation.

FIRST CAUSE OF ACTION

X.

As the pharmacist in charge of a pharmacy that operated without a registered pharmacist on site, Sean Barclay violated Nevada Revised Statute (NRS) 639.220(1) and NRS 639.284(2), as well as Nevada Administrative Code (NAC) 639.945(1)(i) and/or (j), which violations are

grounds for discipline pursuant to NRS 639.210(4), (11), (12) and/or (15) and NAC 639.702, or alternatively, under NRS 639.255, as well as NAC 639.955.

SECOND CAUSE OF ACTION

XI.

As the owner and operator of the pharmacy in which Barclay violated Nevada law, as alleged above, including in the First Cause of Action, Meta Pharmacy Services is responsible for those violations pursuant to NAC 639.945(2), which is grounds for discipline pursuant to NRS 639.210(11) and/or (12), NRS 639.230(5), NRS 639.255, and NAC 639.955.

THIRD CAUSE OF ACTION

XII.

In owning and operating a pharmacy without a registered pharmacist acting as the pharmacist in charge, Meta Pharmacy Services violated NRS 639.220(1) and NRS 639.284(1), which violations are grounds for discipline pursuant to NRS 639.210(4), (11) and/or (12), or alternatively, under NRS 639.255, as well as NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of the Respondent.

Signed this 8th day of March 2019.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements regarding your license and/or certificate of registration. To do so, you must mail to the Board within 20 days of your receipt of this Notice of Intended Action and Accusation a written statement showing your compliance.

Alaska State Board of Pharmacy, Case Number: 2023-000767

On November 16, 2023, the Alaska Board of Pharmacy ("Board of Pharmacy") finalized an Imposition of Civil Fine between the Board of Pharmacy and Meta Pharmacy Services, LLC dba Meta Pharmacy Services, (formerly known as Barclay Luke & Pillai Specialty Pharmacy PLLC dba Meta Pharmacy Services) located at 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Alaska Non-Resident Pharmacy Permit #: 212605).

On or about November 16, 2023, the Board of Pharmacy alleged that Meta Pharmacy Services failed to timely report disciplinary action received in Nevada in 2019 regarding operating a pharmacy with an unregistered pharmacist.

Meta Pharmacy Services acknowledged allegations made by the Board of Pharmacy and agreed to the Imposition of Civil Fine and to pay a $1,000 fine issued by the Board of Pharmacy.

Upon receipt of the fine, and signed Imposition of Civil Fine, the Board of Pharmacy considered the matter closed and took no further action. The Board of Pharmacy has independently chosen not to report this matter to the National Practitioner Data Bank (NPDB), however this information is provided here for transparency.

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2023-000767

I, MATTHEW HOGAN, as an agent for Meta Pharmacy Services, admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Out-of-State Pharmacy License No. 212605, and over this Imposition of Civil Fine.

1. On July 10, 2023, we submitted an initial Out-of-State (OOS) Pharmacy application in reference to License #212605.
2. We failed to properly disclose an April 26, 2019, license disciplinary action from the Nevada State Board of Pharmacy for owning and operating a pharmacy with an unregistered pharmacist for approximately 224 days.
3. This is a violation of AS 08.80.261(a)(6) and 12 AAC 52.920(a)(13).

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.075, AS 08.80.261(a)(6), and 12 AAC 52.920(a)(13) We are agreeing to this Imposition of a Civil Fine of one thousand dollars ($1000) in cash, certified check, or money order payable to the "**State of Alaska**" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

Agent for ~~Meta~~ Pharmacy Services (Signature) — Date: 11/9/2023

SUBSCRIBED AND SWORN TO before me this 9th day of November, 2023, at Las Vegas (city), NV (state).

SEAL

Notary Public in and for Alaska

BH
BH

STEFANI MORRIS
Notary Public, State of Nevada
Appointment No. 21-6315-01
My Appt. Expires Apr 6, 2025

Stefani Morris
Notary Printed Name
My commission expires: 4/6/25

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Meta Pharmacy Services)
)
Respondent)
Case No. 2023-000767

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2023-000767, regarding License No. #212605, for failure properly disclose previous licensing discipline on an initial Out-of-State (OOS) Pharmacy application, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 16th day of November, 2023, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Ashley Schaber
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

California State Board of Pharmacy, Case Number: CI 2023 103924

On September 16, 2024, the California Board of Pharmacy ("Board of Pharmacy") finalized a Citation and Fine ("Citation") between the Board of Pharmacy, and Meta Pharmacy Services, LLC dba Meta Pharmacy Services, (formerly known as Barclay Luke & Pillai Specialty Pharmacy PLLC dba Meta Pharmacy Services) located at 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113.

On or about October 16, 2023, the Board of Pharmacy alleged that Meta Pharmacy Services had operated a pharmacy from approximately January 4, 2022 to September 27, 2023, including dispensing into the state of California, without a current license or registration with the Board of Pharmacy.

Meta Pharmacy Services agreed to the Citation and to pay a $5,000 fine issued by the Board of Pharmacy.

Upon receipt of the fine, and signed Citation, the Board of Pharmacy considered the matter closed and took no further action. The Board of Pharmacy has independently chosen not to report this matter to the National Practitioner Data Bank (NPDB), however this information is provided here for transparency.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

September 16, 2024

META PHARMACY SERVICES
ATTN: PHARMACIST IN CHARGE
8352 W WARM SPRINGS RD #120
LAS VEGAS, NV 89113

RE: CI 2023 103924
META PHARMACY SERVICES
Unlicensed

This is in response to the administrative fine provided to the board for the above referenced citation. The payment has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Citation and Fine Analyst, Suelynn Yee at (916) 518-3013.

Sincerely,

Suelynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

April 04, 2024

DATED MATERIAL ENCLOSED

META PHARMACY SERVICES
ATTN: PHARMACIST IN CHARGE
8352 W WARM SPRINGS RD #120
LAS VEGAS, NV 89113

RE: CI 2023 103924
META PHARMACY SERVICES
Unlicensed

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- May 04, 2024: Unless the Citation is contested payment of fine(s) must be received by the Board.
- April 18, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 04, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By:

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **May 04, 2024.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than April 18, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than May 04, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2023 103924	META PHARMACY SERVICES, Unlicensed

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4112 subd. (a)(b)/Bus. & Prof. Code § 4120 subd. (a)	Nonresident pharmacy: registration required/Nonresident Pharmacy: Registration Required	$5,000.00

CONDUCT:

Nonresident Pharmacy Registration Required – Business and Professions Code section 4120 states, (a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler or third-party logistics provider who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler or third-party logistics provider pursuant to this chapter without registering as a nonresident pharmacy. Business and Professions Code section 4112 states, (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy. (b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed. Specifically, between 1/4/2022 and 9/27/2023, Meta Pharmacy Services, located at 8350 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 sold compounded sterile preparations to California patients. Some of them were administered to patients at Milart Prescription Pharmacy (PHY47582) located at 300 S. Beverly Drive, Suite 100, Beverly Hills, CA 90212, including the following found during an inspection at Milart Prescription Pharmacy on 9/26/2023:

- Biotin 10mg/ml Injectable Solution
- Coenzyme Q10 Injectable Solution
- Glutathione 20% Injection
- Lipo-C Injection
- Vitamin C 50% for Injection
- Vitamin D3 Injectable

Meta Pharmacy Services, located outside the state of California provided dangerous drugs into California without registering as a nonresident pharmacy or obtaining a license from the Board is a violation of BPC 4112 (a) and (b) and BPC 4120(a).

CITATION ISSUED ON: April 04, 2024 | TOTAL AMOUNT OF FINE(S): $5,000.00

PAYMENT OF FINE(S) DUE BY: May 04, 2024

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

AMENDED CEASE AND DESIST

Date: November 3, 2023
Permit No.: Unlicensed
Names: Meta Pharmacy Services
Address: 8350 W Warm Springs Rd Suite 120
Las Vegas, NV 89113

Authority for this Action:

Business and Professions Code Section 4316, subdivision (a), states, "the board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure." Subdivision (b) of that section provides that, whenever the board issues a cease and desist order, the Board must immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

On or about October 16, 2023, the Board issued a cease and desist to Meta Pharmacy Services (Meta). Meta timely appealed the October 16, 2023, cease and desist, and a hearing was scheduled. In order to resolve this matter without the expense and uncertainty of a hearing, this cease and desist order is amended as follows:

Activities under this chapter that require licensure include those set forth in the following regulations:

Business and Professions Code section 4037, subdivision (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

Business and Professions Code section 4112, subdivision (a) any pharmacy located outside this state that ships, mails, or delivers, **in any manner**, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

Business and Professions Code section 4112, subdivision (b) a person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

Business and Professions Code section 4127.2 subdivision (a) a nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

Acts or Omissions Upon Which this Action is Based

Meta Pharmacy Services located at 8350 W Warm Springs Rd Suite 120 Las Vegas, NV 89113 is not licensed in California by the Board.

The Board's investigation has determined that between January 4, 2022, and September 27, 2023, Meta Pharmacy Services may have conducted activities which under this chapter require licensure without obtaining that licensure by filling or dispensing prescription drugs, including sterile compounded drugs, to California-resident patients with prescriptions that were issued by California licensed physicians who do not hold prescribers' licenses in the State of Nevada.

Order

On the basis of the foregoing, the Board, through its Executive Officer, therefore ORDERS: Effective immediately, Meta Pharmacy Services, not licensed as a pharmacy in California, shall cease and desist practicing any activity under this chapter that requires licensure, including shipping, mailing, or delivering **in any manner**, prescription medications to California-resident patients with prescriptions issued by California licensed prescribers who do not hold prescribers' licenses in the State of Nevada.

Unlicensed Entity's Right to be Heard and Procedure

Meta Pharmacy Services waives and gives up its right to a hearing before the president of the Board pursuant to Business and Professions Code section 4316, subdivision (c). Meta Pharmacy Services understands and agrees that this Amended Cease and Desist Order is issued in resolution of the October 16, 2023, cease and desist order, which is now and hereby amended, and stipulates and agrees that the hearing currently scheduled for November 8, 2023, will be cancelled and that this matter is now final.

California State Board of Pharmacy

By: Anne Sodergren, Executive Officer

Signed: _____ Date: 11/6/2023, 2023

Acknowledgement

I have carefully read and fully discussed with counsel the above amended cease and desist order, and withdraw my request for a hearing before the Board President, which is currently scheduled for November 8, 2023, and to waive any further hearing or appeal on this cease and desist order.

By: _____ Date: 11/6/23, 2023
(Signature)

Print name and title: Sean Barclay

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Date: October 16, 2023
Permit No.: Unlicensed
Names: Meta Pharmacy Services
Address: 8350 W Warm Springs Rd Suite 120
Las Vegas, NV 89113

Authority for this Action:

Business and Professions Code Section 4316, subdivision (a), states, "the board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure." Subdivision (b) of that section provides that, whenever the board issues a cease and desist order, the Board must immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

Activities under this chapter that require licensure include those set forth in the following regulations:

Business and Professions Code section 4037, subdivision (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

Business and Professions Code section 4112, subdivision (a) any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

Business and Professions Code section 4112, subdivision (b) a person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

Business and Professions Code section 4127.2 subdivision (a) a nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.
Business and Professions Code section 4127.2 subdivision (b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

Acts or Omissions Upon Which this Action is Based

Meta Pharmacy Services located at 8350 W Warm Springs Rd Suite 120 Las Vegas, NV 89113 is not licensed in California by the Board.

The Board's investigation has determined that Meta Pharmacy Services is conducting activities which under this chapter require licensure without obtaining that licensure by initiating the process of dispensing drugs as follows:

- Meta Pharmacy Services has provided over 900 prescription medications to California patients and doctors.
- Meta Pharmacy Services has provided sterile compounded medications to California patients and doctors.

Order

On the basis of the foregoing, the Board, through its Executive Officer therefore ORDERS: Effective immediately, Meta Pharmacy Services, an unlicensed pharmacy, shall cease and desist practicing any activity under this chapter that requires licensure, including providing prescription medication to California patients.

Unlicensed Entity's Right to be Heard and Procedure

Pursuant to Business and Professions Code Section 4316, subdivision (c), within 15 days of receipt of this notice, Meta Pharmacy Services may request a hearing before the president of the Board to contest this cease and desist order. Any contest of the cease and desist order will comply with the requirements of Section 11425.10 of the Government Code, a copy of which is enclosed. Chapter 5 of the Administrative Procedures Act (commencing at Government Code Section 11500) does not apply to this proceeding. The hearing will be held no later than five (5) days from the date the owner's request for a hearing is received by the Board. The president will render a written decision within five (5) days of the hearing. In the absence of the president of the Board, the vice president of the Board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the Board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

California State Board of Pharmacy

By: Anne Sodergren, Executive Officer

Signed: Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.10.16 13:41:30 -07'00'

Date: October 16, 2023

Acknowledgement

I hereby acknowledge receipt of the above cease and desist order and notice.

By:

Date:

Please return a copy of this signed and acknowledged document to the Board of Pharmacy by fax to 916-574-8618.

Meta Pharmacy Services, LLC - Owners and Officers

Name and Title	Business Address and Telephone	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
OGB Meta III, LLC Parent / Sole Member	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 admin@metapharmacyservices.com	[redacted]	[redacted]	[redacted]	100%
Derek O'Leary President and Treasurer	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 derek@jbncp.com				0%
Sean M. Barclay* Vice President and Secretary	8352 West Warm Springs Rd, Suite 120 Las Vegas, NV 89113 (702) 754-0172 Sean@metapharmacyservices.com				20% Indirect

*Pharmacist Licenses Held

State	Number	Effective Date	Expiration Date
Alaska	226660	11/08/2024	06/30/2026
Idaho	PR71688	07/13/2023	09/30/2025
Iowa	51930	10/09/2023	12/31/2024
Michigan	5302034202	10/09/2006	10/09/2025
Nevada	17303	01/28/2008	10/31/2025

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Meta Pharmacy Services, LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/10/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/19/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412195280826
You may verify this certificate online at https://www.nvsilverflume.gov/home

State of Florida
Department of State

I certify from the records of this office that META PHARMACY SERVICES, LLC. is a limited liability company organized under the laws of the State of Florida, filed on November 22, 2024.

The document number of this limited liability company is L24000492499.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifth day of December, 2024

Secretary of State

Tracking Number: 7589678360CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Meta Pharmacy Services

Pharmacy/Wholesaler License # (if applicable): PH03433

Physical Address: 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Telephone: 844-334-1010 Website: www.metapharmacyservices.com

Licensing Company Email: admin@metapharmacyservices.com

Section 2: Personal Information

First: Sean Middle: M. Last: Barclay

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
John F. Kennedy High School			09/95 - 06/99
Address	**City**	**State**	**Zip**
13505 Kennedy Drive	Taylor	MI	48180
Diploma/Degree obtained, if any			
High School Degree			

School Name			From - To (MM/YY – MM/YY)
Wayne State University			09/99 - 06/06
Address	**City**	**State**	**Zip**
42 W Warren Ave	Detroit	MI	48202
Diploma/Degree obtained, if any			
Bachelor's Degree, Doctorate of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2012-2020		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services			10/14-present	
Business Address	**City**		**State**	**Zip**
8352 W Warm Springs RD, #120	Las Vegas		NV	89113
Phone	**Title**		**Number of Employed Hours**	
844-334-1010	Pharmacist, Pharmacist-in-Charge		20,800	
Description of Duties				
Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/27/2018	04/10/2019	NV	Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-002-RPH-S and 19-002-PH-S	Nevada State Board of Pharmacy

Reason/Charge
Operating a pharmacy without a license

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Nevada State Board of Pharmacy/Meta Pharmacy Services, Sean M. Barclay	Order

Name of Business/Industry/Entity
pharmacy

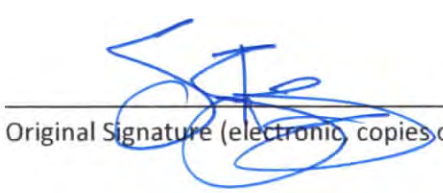
Provide explanation below:

On April 10, 2019 the Nevada State Board of Pharmacy ("Board of Pharmacy") finalized a Findings of Fact, Conclusions of Law and Order ("Order) between the Board of Pharmacy, pharmacist Mr. Sean Barclay and Meta Pharmacy Services, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Nevada Resident Pharmacy Permit #: PH03433).

On or about November 27, 2018, the Board of Pharmacy alleged that Mr. Barclay, acting as a licensed Nevada pharmacist and as the managing pharmacist for Meta Pharmacy Services, had operated a pharmacy from approximately November 1, 2017 to November 29, 2018 without a current license or registration with the Board of Pharmacy.

Mr. Barclay and Meta Pharmacy Services did not oppose the citation. Mr. Barclay agreed to pay the $3,500 personal fine and Meta Pharmacy Services agreed to pay the $7,683.99 facility fine issued by the Board of Pharmacy.

Upon receipt of the fines, and signed Order, the Board of Pharmacy considered the matter closed and took no further action.



Original Signature (electronic copies or stamps not accepted)

12/24/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/16/2023	11/16/2023	AK	Anchorage	Anchorage

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2023-000767	Alaska State Board of Pharmacy

Reason/Charge
Failure to timely report disciplinary action

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Alaska State Board of Pharmacy/Meta Pharmacy Services	Imposition of Civil Fine

Name of Business/Industry/Entity
pharmacy

Provide explanation below:

On November 16, 2023, the Alaska Board of Pharmacy ("Board of Pharmacy") finalized an Imposition of Civil Fine between the Board of Pharmacy and Meta Pharmacy Services, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Alaska Non-Resident Pharmacy Permit #: 212605).

On November 16, 2023, the Board of Pharmacy alleged that Meta Pharmacy Services failed to timely report disciplinary action received in Nevada in 2019 regarding operating a pharmacy with an unregistered pharmacist.

Meta Pharmacy Services acknowledged allegations made by the Board of Pharmacy and agreed to the Imposition of Civil Fine and to pay a $1,000 fine issued by the Board of Pharmacy.

Upon receipt of the fine, and signed Imposition of Civil Fine, the Board of Pharmacy considered the matter closed and took no further action. The Board of Pharmacy has independently chosen not to report this matter to the National Practitioner Data Bank (NPDB), however this information is provided her for transparency

Original Signature (electronic, copies or stamps not accepted)

12/24/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/16/2023	09/16/2024	CA	Sacramento	Sacramento
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CI 2023 103924		California State Board of Pharmacy		
Reason/Charge				
Operating a pharmacy without a license				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
California State Board of Pharmacy/Meta Pharmacy Services			Citation and Fine	
Name of Business/Industry/Entity				
pharmacy				

Provide explanation below:

On September 16, 2024, the California Board of Pharmacy ("Board of Pharmacy") finalized a Citation and Fine ("Citation") between the Board of Pharmacy, and Meta Pharmacy Services, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113.

On or about October 16, 2023, the Board of Pharmacy alleged that Meta Pharmacy Services had operated a pharmacy from approximately January 4, 2022 to September 27, 2023, including dispensing into the state of California, without a current license or registration with the Board of Pharmacy.

Meta Pharmacy Services agreed to the Citation and to pay a $5,000 fine issued by the Board of Pharmacy.

Upon receipt of the fine, and signed Citation, the Board of Pharmacy considered the matter closed and took no further action. The Board of Pharmacy has independently chosen not to report this matter to the National Practitioner Data Bank (NPDB), however this information is provided here for transparency.

Original Signature (electronic, copies or stamps not accepted)

12/24/2024
Date

I, Sean M. Barclay, **certify that as the designated representative for**

Meta Pharmacy Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SB I am at least 21 years of age;
3. SB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sean M. Barclay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean M. Barclay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/24/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, ~~Misty Richardson~~ SB Sean Barclay, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

~~Misty Richardson~~ SB

Original Signature

12/24/2024

Date

Subscribed and Sworn to before me this 24th day of December.

Misty Richardson

Notary Public Signature

MISTY DAWN RICHARDSON
Notary Public, State of Nevada
Appointment No. 24-1238-01
My Appt. Expires Mar 14, 2028

(Seal)

Meta Pharmacy Services
8352 W Warm Springs Road, Suite 120
Las Vegas, NV 89113

Section 11: Personal and Professional History

Nevada State Board of Pharmacy (Case Numbers: 19-002-RPH-S and 19-002-PH-S)

On April 10, 2019 the Nevada State Board of Pharmacy ("Board of Pharmacy") finalized a Findings of Fact, Conclusions of Law and Order ("Order) between the Board of Pharmacy, pharmacist Mr. Sean Barclay and Meta Pharmacy Services, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Nevada Resident Pharmacy Permit #: PH03433).

On or about November 27, 2018, the Board of Pharmacy alleged that Mr. Barclay, acting as a licensed Nevada pharmacist and as the managing pharmacist for Meta Pharmacy Services, had operated a pharmacy from approximately November 1, 2017 to November 29, 2018 without a current license or registration with the Board of Pharmacy.

Mr. Barclay and Meta Pharmacy Services did not oppose the citation. Mr. Barclay agreed to pay the $3,500 personal fine and Meta Pharmacy Services agreed to pay the $7,683.99 facility fine issued by the Board of Pharmacy.

Upon receipt of the fines, and signed Order, the Board of Pharmacy considered the matter closed and took no further action.

By: _____ 12/24/2024

Name: Sean M. Barclay
Title: Pharmacist-in-Charge

Date

Please be advised, the information provided relates to the Applicant's previous ownership.

As the Applicant and the previous ownership share the same dba name, we are providing this information with transparency in mind, to ensure the Board of Pharmacy is aware of these matters.

Further be advised, the Applicant has not had a license investigated, disciplined nor are any investigations or disciplinary actions pending.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

NV Pharmacy or Outsourcing facility license # (if applicable): PH03433

Physical Address: 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Telephone: 844-334-1010 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Sean M. Barclay

Supervising/Managing Pharmacist NV Pharmacist Registration #: 17303

Name of Designated Person(s) as defined by revised USP-797 guidelines: Sean M. Barclay

Email of Designated Person(s): admin@metapharmacyservices.com

Telephone of Designated Person(s): 844-334-1010

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

■ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 10/29/2024

6. What is the frequency of the recertification for the ISO classified areas? every seven months

7. Were there any follow-up items required from the most recent certification report? ■ Yes ☐ No

Follow-up to occur at the next annual inspection in October 2025.

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Biannually

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

please see attached

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Ste. 546

City: Oklahoma City State: OK Zip: 73104

Telephone: (800) 393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Compounded sterile products will be inspected, before dispensing, by supervising pharmacists through a double-check system. (1.) Inspection of CSPs includes: (a.) Visual inspection for particulates and/or cloudiness. The CSP will be examined against a lighted white or black background, or both.; (b.) Verification of prescription orders with the written work order / compounding record (preparation; records). (c.) Verification of ingredients used, including correct amounts and concentrations (d.) Verification of final fill amounts (e.) Verification of aseptic manipulations and sterilization (f.) Package integrity, any leakage observed (g.) Visual inspection of syringes and additive containers used (h.) Correct and complete label: i. Name of patient; ii. Patient location; iii. Correct names, amounts and concentrations of the ingredients; iv. Total volume ; v. Preparation date; vi. Beyond-use date; vii. Route of administration; viii. Storage requirements; ix. Infusion rate when applicable; x. The initials of the final Pharmacist check (i.) Labels for CSPs must be clear, consistent, legible and in compliance with state and federal regulations. (2.) CSPs with visual defects will be immediately discarded. (3.) When the identity and concentrations of ingredients cannot be verified, samples of the CSPs will be assayed. (4.) CSPs that are not immediately dispensed will be stored according to procedure. a. CSPs that are stored, will again be inspected before the CSPs are dispensed.

14. How often do you perform glove fingertip and medial fill testing?

Biannually

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Aseptic technique training will be ongoing; personnel must pass a media-fill test every 6 months. Compounding personnel who fail media-fill test would be re-evaluated. All compounding personnel must successfully complete 3 (three) Initial Gloved Fingertip sampling prior to compounding CSPs for human use. Ongoing GFS to be performed with the preparation of media fill units which is required initially (before compounding CSPs for human use) and every 6 months for compounding staff of pharmacies performing Category 2 compounding. Personnel who have direct oversight of compounding personnel, but do not compound, must complete training initially and every 12 months. Pharmacy Department shall demonstrate, assess, maintain and improve staff competence on an ongoing basis. Personnel must have didactic and practical training. Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see attached policy: 3.020 Cleaning and Maintenance of Non-Sterile Compounding Area

17. Who performs the sterile compounding process at your facility?

Licensed staff members who have documented completion of appropriate competencies.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Sean M. Barclay, Pharmacist-in-Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see attached policy: 1.090 Delivery of Compounded Preparations

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Laminar Flow Hood, Powder Hood, Biological Safety Cabinet		
2. Are you complying with all USP 800 guidelines?	■ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

The Applicant provides education to patients upon admission and on an on-going basis while patients are actively on service.
(a.) Patients are to receive an admission packet, including information explaining how to contact the pharmacy for any concerns or questions.
(b.) Patients are to receive individual consultation as well as ongoing communication with the pharmacists.
(c.) Patients have access to the website, which allows them access to patient specific information.
(d.) Patients have access to pharmacists for any concerns or questions about their medications.
(e.) Patients review and sign a consent form explaining the therapy and medications involved (indication for IT drug(s), side effects, and when to call the pharmacy or physician).
(f.) Patients will be given patient drug information leaflets, that are available, the first time a medication is dispensed or when there is serious risk.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

(1.) On-the-job experiential training from experienced compounding personnel.
(2.) Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities. A PATT for the appropriate risk level of CSPs, and a 3-part initial Glove Fingertip Test must be passed before assuming compounding responsibilities.
(3.) Staff will participate in training and assessment (web-based continuing education for USP 797 compliance) upon hire and annually thereafter.
(4.) Staff will have access to the ASHP Sterile Compounding Library in order to complete a 3- course program with interactive lessons and follow-up testing. This program is completed annually and will include: a. Hand hygiene; b. Garbing procedure for ISO classified environments; c. Cleaning and disinfection of the Ante-area, Cleanroom, and PECs; d. Aseptic technique
(5.) Pharmacy Competency Skills Checklist performed annually
(6.) Bi-annual Aseptic Personnel Assessment Form
(7.) Bi-annual PATT requirement
(8.) Bi-annual Glove Fingertip Sampling
(9.) Instruction on safety procedures
(10.) Instruction on CSPs to include: a. Identification; b. Accurate measuring, weighing, dilution and mixing of ingredients; c. Purification, sterilization; d. Packaging; e. Labeling; f. Storage; g. Dispensing; h. Transport; i. Documentation of the compounding process; j. Sterilization for high-risk CSPs
(11.) Proper use and maintenance of all equipment, including an understanding of HEPA Filtered air flow in ISO classified environments
(12.) Transport of materials to and from the Cleanroom
(13.) Only those individuals who are qualified through license, experience and training to assess sterile compounding skills will conduct competency assessments.
(14.) When improvement activities (written test and media-fill tests) lead to a determination that a person with performance problems is unable or unwilling to improve, the staff member's work assignment may be revised. Further education and training will be required or other corrective action(s) may be taken.
(15.) The staff member will not return to compounding duties until performance problems are resolved.
(16.) The competence assessment program is continuous and ongoing, with reports of competency outcomes available to the Pharmacist-in-Charge.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

please see attached

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Biannually

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

Biannually

5. What is the frequency for completing surface sampling? Monthly
6. What is the frequency for using sporicidal agents? Sporicidal agents are used daily inside PEC's and nonsterile HD room powder hood and table surfaces. All surfaces, including ceilings, walls, and bins undergo monthly terminal cleaning with sporicidal agents.
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component? ☐ Yes ■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method? ☐ Yes ■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean M. Barclay

Name of Person who Completed the Form

Pharmacist-in-Charge

Title

Signature (copies or stamps not accepted)

12/24/2024

Date

Board Use Only	Date Received: 12/30/24 Date Approved: _____ Approved By: _____

Certificate of Compliance

Awarded To:

Meta Pharmacy Services
8352 W. Warm Springs Boulevard, Suite 120
Las Vegas, NV 85705
(702) 250-4406 phone

Testing Completed By:

Controlled Environment Management, LLC
2487 S. Gilbert Rd., Suite 106-610
Gilbert, AZ 85295
(480) 836-4144 phone

This is to certify that the following area(s) have been tested and certified in accordance with ISO 14644 and CETA CAG-003 specifications. The air cleanliness classification designation and testing criteria are listed below.

Area ID: **Pharmacy Compounding Suite**
Date of Testing: October 29, 2024
ISO 14644: Class 7 (Non Haz, Haz, Haz, Ante Rooms)
ISO 14644: Class 8 (Non-Sterile, Gowning Rooms)
Particle Size: ≥ 0.5µm
Area Mode: Dynamic

CEM Project: ATZ241029

CEM

NABP ACCREDITED
COMPOUNDING PHARMACY

Meta Pharmacy Services

located at

8352 W Warm Springs Rd, Ste 120, Las Vegas, NV 89113

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

Risk Level	Drug Description
High	ALPHA LIPOIC ACID 25 MG/ML INJECTION
High	BCAA ISOLEUCINE/LEUCINE/VALINE 15/10/40 MG/ML INJ SOLUTION
High	BIOTIN 10MG/ML INJECTABLE SOLUTION
High	CARNITINE 50% INJECTABLE SOLUTION
High	DEXPANTHENOL 250 MG/ML INJECTABLE SOLUTION
High	GLUTATHIONE 20% INJECTION
High	HYDROXOCOBALAMIN (B12) 10 MG/ML INJ
High	LIPO C 15MG/50MG/50MG/25MG/15MG/5MG (Carnitine, Choline, Inositol, Methionine, Thiamine, Dexpanthenol)
High	LIPO INJECTION (MIC) (Methionine, Inositol, Choline)
High	LIPO-B (MIC-B12) STERILE SOLUTION (Methionine, Inositol, Choline, and Methylcobalamin)
High	METHYLCOBALAMIN 12.5MG/ML INJ
High	MYERS COCKTAIL IV ADMIXTURE
High	NAD+ 1,000MG/50ML VIAL INJECTION
High	NANDROLONE DECANOATE 200 MG/ML GRAPESEED OIL
High	PYRIDOXINE 100 MG/ML INJECTABLE SOLUTION
High	QUADMIX STANDARD INJECTION (Atropine, Alprostadil, Papaverine, Phentolamine)
High	SEMAGLUTIDE/L-CARNITINE 2.5/100MG/ML
High	SERMORELIN 3MG/3ML SOLUTION INJECTION
High	STANOZOLOL 50 MG/ML 'IM' INJECTION
High	SUPER TRIMIX INJ (Alprostadil, Papaverine, Phentolamine)
High	TAURINE 50 MG/ML INJECTABLE SOLUTION
High	TIRZEPATIDE/L-CARNITINE 16.7/100MG PER ML
High	TRIMIX #1 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #3 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #4 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #5 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #6 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRT CYPIONATE-ZINC SULFATE 200-1 MG/ML IN GRAPESEED OIL
High	VITAMIN B COMPLEX INJECTION
High	VITAMIN C 50% FOR INJECTION (Sodium Ascorbate)
High	VITAMIN D3 50000 UNITS/ML 'IM' INJ

Attachment: List of Sterile Compounded Products

Drug Description
ALPHA LIPOIC ACID 25 MG/ML INJECTION
BCAA ISOLEUCINE/LEUCINE/VALINE 15/10/40 MG/ML INJ SOLUTION
BIOTIN 10MG/ML INJECTABLE SOLUTION
CARNITINE 50% INJECTABLE SOLUTION
DEXPANTHENOL 250 MG/ML INJECTABLE SOLUTION
GLUTATHIONE 20% INJECTION
HYDROXOCOBALAMIN (B12) 10 MG/ML INJ
LIPO C 15MG/50MG/50MG/25MG/15MG/5MG (Carnitine, Choline, Inositol, Methionine, Thiamine, Dexpanthenol)
LIPO INJECTION (MIC) (Methionine, Inositol, Choline)
LIPO-B (MIC-B12) STERILE SOLUTION (Methionine, Inositol, Choline, and Methylcobalamin)
METHYLCOBALAMIN 12.5MG/ML INJ
MYERS COCKTAIL IV ADMIXTURE
NAD+ 1,000MG/50ML VIAL INJECTION
NANDROLONE DECANOATE 200 MG/ML GRAPESEED OIL
PYRIDOXINE 100 MG/ML INJECTABLE SOLUTION
QUADMIX STANDARD INJECTION (Atropine, Alprostadil, Papaverine, Phentolamine)
SEMAGLUTIDE/L-CARNITINE 2.5/100MG/ML
SERMORELIN 3MG/3ML SOLUTION INJECTION
STANOZOLOL 50 MG/ML 'IM' INJECTION
SUPER TRIMIX INJ (Alprostadil, Papaverine, Phentolamine)
TAURINE 50 MG/ML INJECTABLE SOLUTION
TIRZEPATIDE/L-CARNITINE 16.7/100MG PER ML
TRIMIX #1 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #3 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #4 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #5 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #6 INJ (Alprostadil, Papaverine, Phentolamine)
TRT CYPIONATE-ZINC SULFATE 200-1 MG/ML IN GRAPESEED OIL
VITAMIN B COMPLEX INJECTION
VITAMIN C 50% FOR INJECTION (Sodium Ascorbate)
VITAMIN D3 50000 UNITS/ML 'IM' INJ
TOBRAMYCIN 1.5% (15 MG/ML) EYE DROP
VANCOMYCIN 2.5% (25 MG/ML) EYE DROPS

CONTROLLED ENVIRONMENT MANAGEMENT, LLC

PHARMACY POWDER HOOD TEST REPORT

Customer	Meta Pharmacy Services			Report No.	ATZ241029-05 Page 1 of 2
Address	8352 W. Warm Springs Blvd., Suite 120			Manufacturer	AirClean Systems
City, State	Las Vegas, NV	Zip	89113	Model	AC740C
Main Contact	Sean Barclay	Phone	(702) 427-2638	Serial No.	AC740C-1378
Alt. Contact	NA	Phone	NA	Building	Main
Department	Pharmacy			Location	Pharmacy

UNIT TEST RESULTS

- [x] Certified
- [ ] Not Certified
- [ ] Service Only
- [x] See Comments

UNIT TESTED TO STANDARD

- [ ] NSF/ANSI 49
- [x] Manufacturer's Specifications
- [ ] Other _____

TESTS COMPLETED (See Page 2 For Test Data)

[ ] Downflow Velocity Profile	[ ] Pass	[ ] Fail
[x] Inflow Velocity Test	[x] Pass	[ ] Fail
[x] Airflow Smoke Pattern Test	[x] Pass	[ ] Fail
[x] HEPA Filter Leak Test	[x] Pass	[ ] Fail
[ ] Cabinet Integrity Test	[ ] Pass	[ ] Fail
[ ] Site Installation Assessment	[ ] Pass	[ ] Fail
[x] Fluorescent Lighting (Function Test)	[x] Pass	[ ] Fail
[ ] Vibration Test	[ ] Pass	[ ] Fail
[ ] Noise Level	[ ] Pass	[ ] Fail
[ ] Electrical - Polarity	[ ] Pass	[ ] Fail
[ ] Other Test(s) _____	[ ] Pass	[ ] Fail

SERVICE COMPLETED

- [ ] Repaired HEPA Filter Leakage
- [ ] Adjusted Airflow/Air Velocities
- [ ] Paraformaldehyde Decontamination (NIH/CDC)
- [ ] Installed New HEPA Filters
- [ ] Installed New Blower Motor
- [ ] Installed New Electrical Component
- [ ] Installed New Fluorescent Bulb(s)
- [ ] Installed New Ultraviolet Bulb
- [ ] Adjusted Pressure Gauge
- [ ] Other Service _____

EQUIPMENT USED

Equipment	Manufacturer	Model No.	Serial No.
Photometer	TEC Services	PH-5	3543
Generator	TEC Services	AG-E3	3412
Anemometer	TSI	966	P20020001

COPIES OF CALIBRATION CERTIFICATES AVAILABLE UPON REQUEST

COMMENTS:

(1) Airflow smoke pattern test performed over work area. Results of the testing reflected no turbulence or refluxing.

SERVICED BY: James Rawls **DATE:** 10/29/24 **RETEST DATE:** Apr-25

PHARMACY POWDER HOOD TEST REPORT

Customer: Meta Pharmacy Services | Report No.: ATZ241029-05 P2/2 | Technician: JR | Date: 10/29/24

DOWNFLOW VELOCITY PROFILE

Downflow Velocity Measurements

	Non-Zoned	Zoned Front	Zoned Center	Zoned Rear	
Acceptance Criteria	NA	NA	NA	NA	fpm
Average Air Velocity	NA	NA	NA	NA	fpm

Length	NA	Downflow Air Volume	NA
Width	NA	Air Density Correction	NA
Area	NA	**Final Test Result**	NA

Comments: NA

INFLOW VELOCITY TEST

Exhaust Velocity Measurements

Length	NA	Avg. Velocity	95 fpm	Inflow Velocity	95 fpm
Width	NA	Exhaust Volume	266 cfm	Acceptance Criteria	≥ 75 fpm
Area	NA	Air Density Correction	1.00	**Final Test Result**	**Pass**

Comments: (1) Digital airflow monitor reading 85 fpm during testing.

Workface Opening Velocity Measurements

										92	92	93	98	99	96	94

Workface Dimensions: 8.5" x 47.5"
Workface Area: 2.80 ft²

HEPA FILTER LEAK TEST

Supply HEPA Filter

Exhaust HEPA Filter

Aerosol Type	PAO
Concentration	13 µg/L
Leakage Detected	< 0.005%
Acceptance Criteria	≤ 0.005%
Total Patch Size	NA
Total Patch %	NA
Final Test Result	**Pass**

Comments: (1) No leaks detected in exhaust HEPA filter.

SITE INSTALLATION ASSESSMENT TESTS

Airflow Alarms	NA
Sash Alarms	NA
Interlocks	NA
Exhaust System	NA
Final Test Result	NA

Comments: NA

AIRFLOW SMOKE PATTERN TEST

Downflow Test	NA
View Screen Retention Test	NA
Work Opening Edge Retention Test	Pass
Sash Wiper Seal Test	NA
Final Test Result	**Pass**

SECONDARY TESTS

Fluorescent Lighting

Background (≤15Fc)	
Operational (Fc)	
Average Light Reading (Fc)	NA
Acceptance Criteria	NA
Final Test Result	NA

Noise Level Test

Noise Level Reading	NA
Ambient Noise Level	NA
Corrected	NA
Acceptance Criteria	NA
Final Test Result	NA

Electrical Tests

Electric#	NA
Ground Resistance (≤0.15 Ohms)	NA
Polarity Test	NA
Ground Fault Interrupter	NA
Final Test Result	NA

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Retail Pharmacy

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Pharmacy DEA#:	FB5538458
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Primary Wholesaler:	McKesson
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	Pharmacy Personnel List complete and accurate. Comments: Completed prior to inspection. Document retained for Inlumon verification.	☒	☐
3.	Controlled Substance Biennial inventory complete and accurate. Comments: Reviewed document dated 7/25/24. Document contains date and time that inventory was completed. Document signed by pharmacist completing form. C-II products separated from remaining controlled substances.	☒	☐
4.	CSOS receiving documents complete and accurate. Comments: Reviewed documents from September 2024. Date and quantity received completed electronically. CSOS document attached to invoice from wholesaler.	☒	☐
5.	Controlled Substance invoices are complete and accurate. Comments: Pharmacist receiving product are signing and dating all invoices. Pharmacist also placing license number on document.	☒	☐
6.	Records of Pharmacy Personnel on duty complete and accurate. Comments: Manual sign-in log. Log contains date, printed name, staff signature, hours worked, temp, and illness symptoms.	☒	☐
7.	Change in Managing Pharmacist controlled substance inventory complete and accurate (if applicable). Comments: N/A	☐	☐
8.	Security of the pharmacy meets all of Nevada Statutes and Regulations.	☐	☒

	Comments: Location has dead-bolt on front door entry. Safe utilized for C-II products. Barrier between public and pharmacy has a barrier less than 5ft tall. Alarm system in place at location. Cameras located throughout pharmacy.		
9.	In-Service training records for pharmacy technicians complete and accurate. Comments: Will review with 2025 inspection.	☐	☐
10.	Immunization CE (1 hour required annually by 10/31) for immunizing pharmacy technicians complete. Comments: N/A – No immunizations at location.	☐	☐
11.	Activity logs for technicians in training complete and accurate. Comments: Reviewed log for Ronalynn Domingo. Document meets all requirements. Employee has completed 1500 hours of training.	☒	☐
12.	Pharmacy labels on medications being dispensed to patients are labeled with an accurate expiration date. Comments:	☒	☐

Section 3: Controlled Substance Audit Report			
Drug Name	Manual count at time of audit	Balance on hand from software system or manual record at time of audit	Discrepancy
Oxycodone 10mg	350	350	0
Oxy/APAP 10/325mg	504	504	0
Morphine Sulfate 15mg ER	162	162	0
Comments: Location utilizes manual perpetual log.			

Section 4: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
Must meet all security requirements of NAC 639.520.	Completed by October 2025.

Additional Comments:
Well prepared for inspection.
10-20% retail prescriptions vs compounded prescriptions.
Utilizing Infinite Dynamics for delivery service. 50% delivery. Patients are receiving toll-free number and product information as part of delivery service.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of sterile compounding personnel available for review with associated risk level. Comments: Document retained for Inlumon verification.	☒	☐
3.	Pharmacy compounds high risk sterile products. Comments:	☒	☐
4.	Most recent ISO classified area certification report available for review. Comments: Reviewed document dated March 2024. All pressures passed testing. Meets all air exchanges. Passed all particle testing. Passed all HEPA filter leak tests.	☒	☐
5.	Glove finger-tip results complete and accurate. Comments: Location is using revised guidelines for finger-tip testing. Reviewed document for Maria Vega dated 4/19/24. Document is signed by both employee and person performing assessment.	☒	☐
6.	Media fill results complete and accurate. Comments: Recommend placing employee name on form as opposed to initials. Reviewed document for Maria Vegas dated 4/19/24. Meets all requirements. All hoods passed testing. Location passed all viable testing. Recertification was due in September 2024. CEM/TSS scheduled to come out on 10/29/24 for testing.	☒	☐

7.	Cleaning log completed and available for review for ISO classified areas. Comments: Using manual cleaning log. Document contains initials of person performing compounding. Location is using Pre-empt daily and Peridox monthly.	☒	☐
8.	Compounding record is signed by both technician performing compounding and pharmacist who performs final verification. Comments: Manual document is signed by pharmacist and person completing compounding.	☒	☐
9.	Annual competency documentation complete and accurate. Comments: Reviewed document for Maria Vega dated 4/19/24. Meet all requirements.	☒	☐
10.	Pharmacy assigns beyond use dates in excess of USP-797 guidelines. Comments: Following all revised USP-797 guidelines.	☐	☒
11.	Bubble point testing results complete and accurate if applicable. Comments: Bubble point testing and results are attached to compounding record. List both threshold and actual results on form. Location would discard product with failed bubble point testing.	☒	☐
12.	Biological indicator results complete and accurate if applicable. Comments: BI results documented on compounding record and separate log.	☒	☐
13.	Sterility, Potency, and Endotoxin results available for any products requiring such documentation. Comments: Location is performing sterility and endotoxin testing through ARL. Location plans on following Category 2 with sterility testing.	☒	☐
14.	Pharmacy performs hazardous sterile drug compounding. Comments: Location is compounding hormones and mitomycin	☒	☐
15.	Hazardous compounding is performed in a BSC or CACI. Comments:	☒	☐
16.	Documentation of initial and ongoing training for hazardous compounding staff is available for review. Comments: Specific training for staff members. All employees must sign document regarding risks associated with hazardous compounding.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
No follow-up required.	

Additional Comments:
Confirmed that location is not doing any office use compounding.
Well prepared for inspection.
Location has been through multiple FDA, NAPB, and NVBOP inspections. Location may go through another NABP inspection in 2025.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

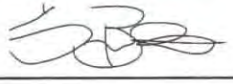
John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X 

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Non-Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of non-sterile compounding personnel available for review. Comments: Retained for Inlumon verification.	☒	☐
3.	Most recent certification report for powder hoods available for review. Comments: Powder hood certified in March 2024. CEM/TSS will recertify again on 10/29/24.	☒	☐
4.	Annual competency documentation complete and accurate. Comments: Reviewed non-sterile competency assessment for Maria Vega. Last assessment performed on 9/6/23. Competency is past due at this time. See notes below.	☐	☒
5.	Pharmacy assigns beyond use dates in excess of USP-795 guidelines. Comments:	☐	☒
6.	Pharmacy performs potency testing on a sampling of products for validation of compounding process. Comments: Not currently. PIC states that they may this in the near future.	☐	☒
7.	Master formulations meet regulatory requirements. Comments: All master formulations come from Medisca.	☒	☐

8.	Compounding worksheets meet regulatory requirements. Comments: Contains name of the person that performs the compounding and the pharmacist that verified the product. BUD is listed on worksheet.	☒	☐
9.	Pharmacy performs hazardous non-sterile drug compounding. Comments: Hormone compounding only. PIC states that they are ready to implement USP-800.	☒	☐
10.	If performing non-sterile hazardous drug compounding there is documentation of initial and ongoing competency for personnel performing this activity. Comments:	☒	☐
11.	Documentation of cleaning records for non-sterile compounding area. Comments: Manual cleaning record available for review. Location is using Pre-Empt and Peridox for cleaning agents in the area.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
PIC to confirm that all non-sterile compounding employees have completed their competency assessment within the last 12 months.	**ASAP**

Additional Comments:
Separate and complete area for non-sterile compounding.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – jcastaldo@pharmacy.nv.gov
Leo Basch – lbasch@pharmacy.nv.gov
Joe Dodge – j.dodge@pharmacy.nv.gov

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – m.lee@pharmacy.nv.gov
Jenine Davis – jmdavis@pharmacy.nv.gov

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

9E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: N/A
	☐ Name Change* (If only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RENEW CARE PHARMACY

Physical Address: 2835 SOUTH JONES BLVD #3

City: LAS VEGAS State: NV Zip: 89146

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 702-985-9120 Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: ILYLARC@GMAIL.COM

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): YVONNE NKWEN-TAMO

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18959

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: YVONNE NKWEN-TAMO	NV Pharmacist Registration #: 18959
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: YVONNE NKWEN-TAMO

Business Name: RENEW CARE PHARMACY

Business Address: 2835 SOUTH JONES BLVD #3

City: LAS VEGAS State: NV Zip: 89146

Telephone: 702-985-9120 Email: ILYLARC@GMAIL.COM

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy Manager (title) for RENEW CARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

YVONNE NKWEN-TAMO

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2 25 25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, YVONNE NKWEN-TAMO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager (title) for RENEW CARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of February, 2025

Notary Public

CRIS GONZALEZ
NOTARY PUBLIC•STATE OF NEVADA
Appointment Recorded in Clark County
No: 20-9932-01
Expires November 20, 2028

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: YVONNE NKWEN-TAMO Pharmacist Registration #: 18959

Pharmacy Name: RENEW CARE PHARMACY

Initial each statement below to indicate you have read and agree with the following:

YN I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

YN I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

YN I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

YN I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

YN I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

2 25 25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 2 25 25

Board Use Only	Date Received: 3/4/25	Amount: $500 cc

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RENEW CARE PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2835 SOUTH JONES BLVD #3

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-985-9120 Website N/A

Licensing Company Email ILYLARC@gmail.com

Section 2: Personal Information

First Yvonne Middle _____ Last Nkwen-Tamo

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences			08/10-06/13	
Address		City	State	Zip
10920 S River Front Pkwy		South Jordan	UT	84094
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
University of Utah			08/99-08/02,8/05-8/10	
Address		City	State	Zip
201 Presidents Circle		Salt Lake City	UT	84112
Diploma/Degree obtained, if any				
BS Mathematics				
School Name			From - To (MM/YY – MM/YY)	
Sacramento State University			12/03-06/05	
Address		City	State	Zip
6000 J St.		Sacramento	CA	95841
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
American River College			08/02-12/03	
Address		City	State	Zip
4700 College Oak Dr		Sacramento	CA	95841
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY	
East High School			03/97-06/99	
Address		City	State	Zip
840 South 1300 East		Salt Lake City	UT	84102
Diploma/Degree obtained, if any				
High School Diploma				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/16-Present	[redacted]	Henderson	NV	[redacted]
01/15-10/16		Henderson	NV	
10/13-01/15		Bullhead City	AZ	
06/13-10/13		Turlock	CA	
08/10-06/13		Salt Lake City	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Goodwill Pharmacy, Inc			05/24-Present
Business Address	**City**	**State**	**Zip**
2610 S. Jones Blvd. #3	Las Vegas	NV	89146
Phone	**Title**		
702-213-3102	Managing Pharmacist		

Description of Duties

Provide comprehensive patient care by processing and accurately dispensing Rx orders, counsel patients regarding health care and Rx needs.

Business Name			From - To (MM/YY – MM/YY)
Fort Mohave Indian Health Center			01/23-01/24
Business Address	**City**	**State**	**Zip**
1607 Plantation RD	Mohave Valley	AZ	86440
Phone	**Title**		
928-346-4679	Pharmacist		

Description of Duties

Reviewed patients medication profile for appropriateness and effectiveness, prepares and dispenses medication to patients, conducts medication profile reviews for safety and efficacy, provides patient counseling as needed

Business Name			From - To (MM/YY – MM/YY)
Sam's Club Pharmacy			05/20-07/22
Business Address	**City**	**State**	**Zip**
8080 West Tropical Pkwy	Las Vegas	NV	89149
Phone	**Title**		
702-515-7214	Pharmacy Manager		

Description of Duties

Provided comprehensive patient care by processing and accurately dispensing Rx orders, counsel patients regarding health care and Rx needs, immunization, improved quality and patient adherence via MTM and counseling patients

Business Name			From - To (MM/YY – MM/YY)
Sam's Club Pharmacy			04/15-05/20
Business Address	**City**	**State**	**Zip**
600 Hwy 95	Bullhead City	AZ	86429
Phone	**Title**		
928-754-3961	Pharmacy Manager		

Description of Duties

Provided comprehensive patient care by processing and accurately dispensing Rx orders, counsel patients regarding health care and Rx needs, immunization, improved quality and patient adherence via MTM and counseling patients

Business Name			From - To (MM/YY – MM/YY)
Smith's Pharmacy			11/13-04/15
Business Address	**City**	**State**	**Zip**
1775 Lakeside Dr	Bullhead City	AZ	86442
Phone	**Title**		
928-763-8777	Pharmacist		

Description of Duties

Reviewed patients medication profile for appropriateness and effectiveness, prepares and dispenses medication to patients, conducts medication profile reviews for safety and efficacy, provides patient counseling as needed

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yvonne NKwen-Tamo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/25/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Yvonne NKwen-Tamo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/25/25

Date

Subscribed and Sworn to before me this 25 day of February 2025.

Notary Public Signature

CRIS GONZALEZ
NOTARY PUBLIC•STATE OF NEVADA
Appointment Recorded in Clark County
No: 20-6932-01
Expires November 20, 2028

(Seal)

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **ILY-LARC LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/12/2023, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/25/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502255469531
You may verify this certificate online at https://www.nvsilverflumc.gov/home

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: veterinary compounding	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FW4366793 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: veterinary

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday*on call	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

Physical Address: 5301 Young Street

City: Bakersfield State: CA Zip: 93311

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (661) 377-3333 Toll Free # (NAC 639.708, NRS 639.23286): (877) 734-3338

Fax: 856-491-4365 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewood.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Samra Wussow

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Ragini Shah	NV Pharmacist Registration #: 13594
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Wedgewood Holdings Inc.

Corporation/Organization Name: Wedgewood Holdings Inc.

Mailing Address: 405 Heron Drive, Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Email: licensing@wedgewoodpharmacy.com

Contact Person Name: Joseph Costa, President & Chief Operating Officer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Maria Kraus, Chief Financial Officer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/19/2024
Date

Board Use Only	Date Received: 11/21/24	Amount: $500-CC

Section 3 – Company History

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to pharmaceuticals industry?

I. Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Swedesboro, NJ Location

03/19/2015 – MN/MI/AL Consent Orders

On March 19, 2015, Wedgewood entered into a consent order with the Minnesota Board of Pharmacy ("*Minnesota Consent Order*"). Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("*Michigan LARA*") and the Alabama Board of Pharmacy ("Alabama BOP") to resolve "sister state" actions that arose out of the Minnesota Consent Order.

The basis for the Minnesota Consent Order are as follows:

Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood from its NJ location, dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a $10,000 civil penalty but admitted no wrongdoing.

Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama Consent Order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibitions on sister state actions.

10/22/2015 – New Jersey Consent Agreement

On October 22, 2015, Wedgewood Village Pharmacy, Inc., entered into a Consent Agreement with the New Jersey Board of Pharmacy resolving a dispute between the parties on the application of "beyond use dating" regulations for sterile compounds.

This is the same order that is referenced on the Swedesboro, NJ facility's home license however, per the terms of the Agreement, it is not to be construed as discipline and any reimbursement paid to the Board is not considered a fine or other sanction.

10/13/2017 – California Citation & Fine

Issued as a result of an investigation by the CA BOP into an unlicensed individual who fraudulently set up an account with Wedgewood as a veterinarian using valid prescriber license information he acquired unlawfully. An administrative citation was issued and Wedgewood paid a nominal fine.

07/20/2018 - DEA Memorandum of Agreement

While Wedgewood does not consider there to be a restriction on its handling of CDS or disciplinary action, however, out of an abundance of caution, Wedgewood is disclosing the following:

As a condition of issuing Wedgewood located in Swedesboro, New Jersey a DEA manufacturer registration, Wedgewood and the DEA entered into a Memorandum of Agreement ("MOA") for a period of five years (until July 20, 2023) during which Wedgewood agreed not to use the DEA manufacturer license to manufacture or distribute controlled substances for human use. Wedgewood obtained a DEA manufacturer registration for the sole purposes of providing controlled substance compounds solely for veterinarians to use for office use.

12/5/2018 – California Citation

The California Board of Pharmacy issued a non-disciplinary, Administrative Citation with no penalty or fine based on a California Board inspector's interpretation of California regulations. In the Inspector's opinion, providing a 15ml ophthalmic container to a veterinarian for office use exceeded the "reasonable quantity" limitation for office use compounds.

Wedgewood discontinued sales of all 15ml ophthalmic container for office use to California veterinarians. The Board issued a Close Out letter on March 1, 2019. No penalty or fine was assessed.

6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837
MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:
Metro and Non-Metro: 800-627-3529
E-Mail Address: Pharmacy.Board@state.mn.us
Web Site: www.pharmacy.state.mn.us

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

Gregory P. Bulinski
Attorney
Bassford Remele
33 South Sixth Street, Suite 3800
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

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Sincerely,

Cody Wiberg

Cody Wiberg, Pharm D, MS, RPh
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remele and Rachael G. Pontikes, Esq., of Dunn Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 30 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY KLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

IN THE MATTER OF:	BEFORE THE ALABAMA STATE BOARD OF PHARMACY
WEDGEWOOD VILLAGE PHARMACY, LLC	
Non-Resident Pharmacy Permit Number: 112625	CASE NO: 16-L-0066

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as Exhibit "A."

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.

2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: [signature]

ITS: President & CEO

[signature]

Jennifer Clark, attorney for Wedgewood Village Pharmacy, LLC

DONE this the ____ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF: WEDGEWOOD VILLAGE PHARMACY, LLC Non-Resident Pharmacy Permit Number: 112625	BEFORE THE ALABAMA STATE BOARD OF PHARMACY CASE NO: 16-L-0086

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC
405 Heron Drive
Suite 200
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on _____ _____, 2016 at _____m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of

the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the _____ day of _____, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goelz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Hassford Remele and Rachael O. Pontikes, Esq., of Duane Morris.

III.

FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.

5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.

6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

IV.

ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of $10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedures:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

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c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

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e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

11. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

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16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

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18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

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DATA PRACTICES NOTICES

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20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MARCY BLISS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KAREN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January, 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT "B"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Wedgewood Pharmacy, Non-Resident Pharmacy
License Number: 262173

STIPULATION AND
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

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EXHIBIT A page 1 of 2

III.

FACTS

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ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

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EXHIBIT A page 2 of 7

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

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a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

EXHIBIT A page 3 of 7

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

EXHIBIT A PAGE 4 of 7

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

EXHIBIT A page 5 of 7

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

EXHIBIT A page 6 of 7

CONSENT:

MARCY BLESS, PRESIDENT
Wedgewood

Dated: 1/13/15

BOARD OF PHARMACY
COMPLAINT REVIEW PANEL

KARRN BERGRUD
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21st day of January 2015.

MINNESOTA BOARD
OF PHARMACY

CODY WIBERG
Executive Director

EXHIBIT A page 7 of 7

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 5/31/16

Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 5/31/2016

EXHIBIT "C"

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.
License Number: 53-01-008041 File Number: 53-15-137238

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.

3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a $10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

COUNT I

The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Geedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

Kim Gaedeke, Acting Director
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-16-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Wedgewood Village Pharmacy, Inc.
License No. 58-01-008041

Complaint No. 58-15-137238

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED $500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 58-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division -- Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.

2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.

B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.

C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read, understand and agree with the terms of the consent order.

AGREED TO BY:

Kelly K. Elizondo

Kelly K. Elizondo (P45584)
Assistant Attorney General
Attorney for Complainant
Dated: 4-1-2016

AGREED TO BY:

Alison Lynch, Pharmacist-in-Charge
Wedgewood Village Pharmacy
Respondent
Dated: 3/31/16

Alan T. Rogalski (P44550)
Attorney for Respondent
Dated: 3/31/2016

MDH:6772746.1

JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street 5th Floor
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
Tel. No. (973) 648-4730

FILED
OCT 22 2015
BOARD OF PHARMACY

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF
THE REGISTRATION OF

WEDGEWOOD VILLAGE PHARMACY, INC.
Registration No.:28RS00316800

TO OPERATE A PHARMACY
IN THE STATE OF NEW JERSEY

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey Board of Pharmacy ("the Board") upon receipt of reports of inspection of the facility at Wedgewood Village Pharmacy, Inc. ("Wedgewood") which occurred on November 14 and 15, 2012. The reports document potential violations of the Board's regulations regarding sterile compounding. Wedgewood engages in high risk sterile compounding.

Among other things, the inspection reports highlighted routine professional practices suggesting that thousands of units of medication were dispensed with disregard for the following regulatory requirements:

- Use-by dates exceed 30 days after preparation in violation of N.J.A.C. 13:39-11.11.

- Failure to include date and time of preparation on prescription labels in violation of N.J.A.C. 13:39-11.10(a)(1).

- Failure to include the use-by date and use-by time on prescription labels as required by N.J.A.C. 13:39-11.10(a)(7).

No evidence of contamination was found. Wedgewood denies the allegations of violations and has been fully cooperative with the Board's investigation. There have been significant changes in management of Wedgewood since the time of the events in question. The pharmacy permit holder at the time of these events is now deceased and his wife now holds the permit. Wedgewood has agreed to replace the registered pharmacist-in-charge. Wedgewood represents that it is now in compliance with New Jersey statutes and regulations and with the USP guidelines. Wedgewood further represents that 100% of all sterile compounds are currently being tested for sterility and that all use-by dates are properly supported. Accordingly, the Board has determined that the monitoring requirements imposed herein are sufficient to protect the public health, safety and

welfare.

The parties, having agreed to resolution of this matter without formal proceedings, and Wedgewood, having agreed and given voluntary consent to the within order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22nd day of OCTOBER, 2015,

ORDERED AND AGREED that

1. Wedgewood shall contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. For the purposes of this Order, LDT Health Solutions, Inc. is an approved Monitor. Within 30 days of the entry of this Order, the Monitor shall furnish the Board directly with a report which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Wedgewood shall conduct environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi and make these test results available to the Monitor prior to the Monitor issuing its report and directly to the Board. Wedgewood shall continue to contract with the Monitor and the Monitor will submit reports directly to the Board on the first day of each month until the Monitor

reports directly to the Board that Wedgewood has complied with all recommendations made by the Monitor and is operating in full compliance with all Board regulations and USP standards. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Wedgewood.

2. Within 30 days of the entry of this order, Wedgewood shall appoint a new pharmacist-in-charge and shall ensure that a pharmacist with sterile compounding expertise (either the pharmacist-in-charge or another employee) directly supervises the daily sterile compounding operations to further ensure the quality and integrity of their products. "Directly supervise" for the purpose of this paragraph means ensure that all proper checks and balances are being performed during the compounding process; help identify and eliminate errors and mistakes; ensure training and testing of personnel testing is occurring; and generally help to ensure that proper aseptic technique is being used to help implement a Quality System and Environment to produce compounded sterile product.

3. Prior to hiring any pharmacist-in-charge or pharmacist to directly supervise daily sterile compounding operations, Wedgewood shall ensure that the individual is competent and that his/her license is not restricted in such a way as to preclude them from fulfilling their job responsibilities.

Wedgewood shall not hire an individual to be pharmacist-in-charge or to directly supervise the daily sterile compounding operations if Wedgewood is aware that the individual is subject to a pending Board investigation.

4. Wedgewood agrees to pay the Board the sum of $500,000.00 in two equal installments due on or before November 31, 2015 and December 31, 2015. This payment will reimburse the Board for attorney's fees and investigative costs and the remainder will be applied toward the Board's ongoing efforts to inspect, investigate and educate pharmacies involved in sterile compounding. Wedgewood and the Board acknowledge and agree that the payment described herein is not a fine, sanction, warning letter or penalty, or payment in lieu thereof. Payment shall be made by bank check, money order, wire transfer or credit card made payable to the New Jersey Board of Pharmacy.

5. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability of the pharmacy.

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr. RPh
Thomas F.X. Bender,
R.Ph., President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Ludmilla P Malmberg
Ludmilla P Malmberg, Owner
and Permit Holder of
Wedgewood Village Pharmacy

Consent as to form and entry:

Angelo Cifaldi, Esq.
Attorney for
Wedgewood Village Pharmacy

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 13, 2017

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 12, 2017: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 27, 2017: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 12, 2017: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 12, 2017.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 27, 2017 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 12, 2017 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	$1,000.00

CONDUCT:

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

CITATION ISSUED ON: October 13, 2017 | TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 12, 2017

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2017 77042
WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2017 77042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On October 13, 2017, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7017 0530 0001 1516 2087

I declare under penalty of perjury that the forgoing is true and correct.

Executed on October 13, 2017, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: WEDGEWOOD VILLAGE PHARMACY LLC

License No: NRP 1826

Citation Number : CI 2017 77042

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check [✓] I contest the Citation and request an Office Conference.

Check One:

[✓] I contest the entire Citation or

[ ] specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name: Marcy Ann Bliss

Signature: [signature] Dated: 10/26/17

Address of Service: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: (Business) (856) 832-1303 Residence: (609) 320-5050

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

UPS
1Z 54E 74601
0470 45 82
Tracking #
10/26/17 3:11pm

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

October 23, 2017

Wedgewood Village Pharmacy
Attention: Alison Lynch
405 Heron Dr., Ste. 200
Swedesboro, NJ 08085

RE: Complaint Investigation CI 2016 72146

Dear Pharmacist-in-Charge:

The Board of Pharmacy has completed its investigation of Wedgewood Village Pharmacy.

As a regulatory agency, when conducting an investigation, the Board must adhere to violations prohibited in pharmacy law. Specifically, the information and documentation obtained during the course of an investigation must clearly demonstrate that a violation of pharmacy law occurred.

The Board's analysis of the information and documentation received did not identify sufficient evidence to determine that a violation of pharmacy law occurred. Accordingly, the Board is closing the matter and will be taking no action against the pharmacy or its licensees.

Although we are closing this matter, please be advised that it is your professional responsibility to assure compliance with all pharmacy laws.

We would like to thank you for your cooperation and assistance. If you should have any questions, please contact the Board at the above address or telephone number.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By

Tina Rojas
Complaint Unit Analyst

Visit our website at www.pharmacy.ca.gov

07/20/2018 - DEA Memorandum of Agreement

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
NEW JERSEY DIVISION
CAMDEN RESIDENT OFFICE

IN THE MATTER OF:

Wedgewood Village Pharmacy, LLC — DEA Application# W15007898E
Wedgewood Animal Wellness, LLC — DEA Application# W17088272E
405 Heron Drive
Swedesboro, NJ 08085

MEMORANDUM OF AGREEMENT

On or about 2/5/2015, the Drug Enforcement Administration (DEA) received an application for controlled substance registration (DEA control number W15007898E) from Wedgewood Village Pharmacy, LLC 405 Heron Drive, Swedesboro, NJ 08085. On or about 8/18/2017, DEA received another application for controlled substance registration (DEA control number W17088272E) from Wedgewood Animal Wellness LLC, 405 Heron Drive, Swedesboro, NJ 08085.

This Memorandum of Agreement (MOA) between the DEA and Wedgewood Village Pharmacy LLC establishes terms and conditions under which the DEA will issue a registration to Wedgewood Village Pharmacy LLC as a Manufacturer to handle Schedules III through V controlled substances subject to the terms set forth below in this Memorandum of Agreement. This MOA applies only to the manufacturing registration to be issued to Wedgewood Village Pharmacy LLC.

Wedgewood agrees to enter into this MOA with the DEA for a period of five (5) years from the date the MOA is signed and fully executed. The MOA shall be considered fully executed when all parties to the MOA have signed and dated the MOA.

Wedgewood agrees to not manufacture or distribute any controlled substances for human use under the DEA issued manufacturing registration.

Wedgewood agrees to contact DEA immediately if there is any change to their business practice of selling controlled substances for animal use only pursuant to their DEA issued manufacturing registration.

Wedgewood shall abide by and obey all federal, state, and local laws and requirements relating to controlled substances.

Wedgewood agrees to immediately notify DEA if there is any change of status in its State of New Jersey license and/or State Controlled Dangerous Substance license, including any actions filed against these licenses.

Wedgewood agrees to allow DEA to conduct onsite inspections, including inspections of its controlled substances records, without prior notice pursuant to a Notice of Inspection of Controlled Premises and without requiring DEA to obtain an Administrative Inspection Warrant, Search Warrant, or other means of entry

Wedgewood agrees that this MOA constitutes the entire agreement between Wedgewood and DEA, and may only be modified or amended by a subsequent document executed in the same manner by both parties in writing.

Wedgewood shall report any professional, civil, or criminal action concerning controlled substances that is pending or taken against the firm by any state, federal, or professional agency or governing body to DEA, Camden Resident Office.

Wedgewood shall maintain a complete and accurate record of all controlled substances manufactured or distributed pursuant to this manufacturing registration.

Wedgewood agrees by executing this MOA, it waives judicial review, and will not challenge or contest the validity of any terms or conditions of this agreement.

The parties further agree that should Wedgewood violate any terms or conditions of this agreement, such violation may constitute grounds for the revocation, or the revocation and immediate suspension, of Wedgewood's DEA manufacturing registration. Nothing in this MOA shall preclude Wedgewood from contesting any subsequent Order to Show Cause, or Order to Show Cause and Immediate Suspension, of its DEA manufacturing registration as permitted under the Controlled Substances Act and the Administrative Procedure Act. Nothing in this MOA shall be construed as a waiver on the part of DEA to utilize any violations, past or subsequent, as grounds for revocation of Wedgewood's DEA manufacturing registration, either by themselves or in conjunction with other grounds, in the event that future DEA administrative proceedings become necessary. Furthermore, DEA is not precluded from introducing this MOA at any subsequent DEA administrative proceeding.

DEA agrees to promptly approve Wedgewood's application for a manufacturing registration, control# W15007898E, upon the signing of this MOA by both parties.

The parties agree that Wedgewood's application, control# W17088272E is withdrawn effective the execution of this agreement.

The responsible Wedgewood official below acknowledges and states that s/he has read the foregoing and understands and agrees with the contents herein and that s/he has signed this MOA.

The parties enter into this MOA with the understanding that the Drug Enforcement Administration and Wedgewood Village Pharmacy LLC will abide by its contents in good faith.

Wedgewood Village Pharmacy, LLC — Date: 7/20/18

FOR THE DRUG ENFORCEMENT ADMINISTRATION

Nancy Coffey — Date
Diversion Program Manager
New Jersey Division

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2016 73882
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2016 73882	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NSC 100970 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NSC 100970, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7938

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

December 05, 2018

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2018 82132
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- December 19, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- January 04, 2019: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Christina Metzen, Associate Enforcement Analyst at (916) 574-7924.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2018 82132	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (c)(1)	A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber...
CCR, Title 16, § 1735.2 subd. (c)(4)	Credible basis for concluding compunded drug preparation is a reasonable quautity for office use...

CONDUCT:

California Code of Regulations section 1735.2 subsection (c)(1) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished order #s SO-WO00513166, SO-WO0512562 and SO-WO00513661 for prescriber office use without documentation, prior to furnishing, that listed the number of patients seen or to be seen in the prescriber's office and the quantity for each patient that was sufficient for office administration. This is a violation of pharmacy law.

California Code of Regulations section 1735.2 subsection (c)(4) states a "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice. Wedgewood Village Pharmacy LLC NRP 1826 was non-compliant. Specifically, between 4/1/2017 and 4/1/2018, Wedgewood Village Pharmacy LLC NRP 1826, located at 405 Heron Drive #200, Swedesboro, New Jersey, furnished over 22000 units of compounded ophthalmic drops sized 10ml to 30ml for prescriber office use into California with the pharmacist not having a credible basis to conclude this was a reasonable quantity for office use, considering the intended use of the ophthalmic drops and the nature of the prescriber's practice. This is a violation of pharmacy law.

CITATION ISSUED ON: December 05, 2018

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On December 05, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7018 0680 0000 1183 7945

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 05, 2018, at Sacramento, California.

DECLARANT
Christina Metzen
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2018 82132
NRP 1826

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2018 82132 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NRP 1826
CITATION AND FINE CI 2018 82132

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4678

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 1, 2019

CERTIFIED MAIL

Wedgewood Village Pharmacy LLC
Attn: Marcy Ann Bliss, CEO
405 Heron Dr. Suite 200
Swedesboro, NJ 08085

RE: CI 2016 73882
NSC 100970

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation CI 2016 73882 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

No fine has been assessed with this citation and no proof of abatement has been ordered. The Citation shall now become the final order of the Board. Please be advised that this citation will become a part of the board's records and constitute a public record for purposes of disclosure.

Please contact Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely,

Thomas P. Lenox

Thomas P. Lenox
Chief of Enforcement
Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Wedgewood Village Pharmacy LLC, NSC 100970
CITATION AND FINE CI 2016 73882

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. 1625 North Market Boulevard, Suite N219, Sacramento, CA, 95834.

On March 1, 2019 I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO.
Wedgewood Village Pharmacy LLC Attn: Marcy Ann Bliss, CEO 405 Heron Dr. Suite 200 Swedesboro, NJ 08085	7018 0680 0000 1183 4685

I declare under penalty of perjury that the forgoing is true and correct.

Executed on March 1, 2019, at Sacramento, California.

Jennifer Sevilla

DECLARANT
Jennifer Sevilla
Associate Enforcement Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			**281**	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**	**$2,500.00**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021	

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

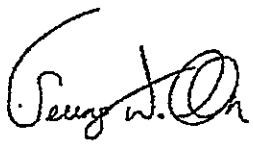
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970	
Respondents.	

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:
By: MARCY ANN BLISS Marcy Ann Bliss
25BA168EA209425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:
Derek Shaffer
DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7286
WEDGEWOOD VILLAGE PHARMACY LLC; **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	**ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

....

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

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D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number CI 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number CI 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

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37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

///

3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "WEDGEWOOD PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE NOT HAVING BEEN CANCELLED OR REVOKED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF FORMATION, FILED THE TWENTY-SECOND DAY OF JANUARY, A.D. 2016, AT 1:18 O`CLOCK P.M.

CERTIFICATE OF MERGER, FILED THE THIRD DAY OF JUNE, A.D. 2016, AT 11:57 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE FOURTH DAY OF JUNE, A.D. 2016 AT 5 O'CLOCK P.M.

CERTIFICATE OF CHANGE OF REGISTERED AGENT, FILED THE TWENTY-SEVENTH DAY OF SEPTEMBER, A.D. 2017, AT 5:34 O`CLOCK P.M.

CERTIFICATE OF MERGER, FILED THE SEVENTEENTH DAY OF JULY, A.D. 2018, AT 11:04 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

5944344 8310

SR# 20244587936

Authentication: 202728863

Date: 01-18-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

CERTIFICATE OF MERGER, FILED THE TWENTY-SECOND DAY OF APRIL, A.D. 2024, AT 10:29 O`CLOCK A.M.

CERTIFICATE OF AMENDMENT, CHANGING ITS NAME FROM "WEDGEWOOD VILLAGE PHARMACY, LLC" TO "WEDGEWOOD PHARMACY LLC", FILED THE TWENTY-SIXTH DAY OF APRIL, A.D. 2024, AT 11:06 O`CLOCK A.M.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 10:58 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:03 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:08 O`CLOCK A.M.

5944344 8310

SR# 20244587936

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202728863

Date: 01-18-25

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:11 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:13 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:19 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

5944344 8310

SR# 20244587936

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202728863

Date: 01-18-25

Delaware

The First State

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:21 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:24 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

CERTIFICATE OF MERGER, FILED THE TWENTY-NINTH DAY OF APRIL, A.D. 2024, AT 11:25 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTIETH DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID LIMITED LIABILITY COMPANY, "WEDGEWOOD PHARMACY LLC".

5944344 8310

SR# 20244587936

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202728863

Date: 01-18-25

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

5944344 8310

SR# 20244587936

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202728863

Date: 01-18-25

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy Clinic Exempt Hospital Wholesaler Hypodermic

Date: 12/6/2023 Inspector: Jeff Shinoda

Firm: PRECISION EQUINE LLC Phone: (661) 377-3333

Address: 5301 YOUNG ST City: BAKERSFIELD Zip: 93311

Ownership: CORPORATION

Permit #: PHY59100 LSC101853 Permit Exp: 12/9/2023 DEA#: FP1992696 DEA Exp: 3/31/2025

Date of Self Assessment Form: 6/30/2023 Other Permit #: N/A Date of DEA Inventory: 4/27/2023

Hours M-F: 8:15AM-5:15PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC **SHAUNA M DOHERTY** RPH65896 Administrator

RPH Consultant

Staff RPH Name:	License #:
SAMRA D WUSSOW	RPH57319
PHU H DINH	RPH62659
MARY WAHBALLA F HABIB	RPH84267
CHRISTINE R DELL'ACQUA	RPH40184
RANIA A SHENODA	RPH87301
PANIZ AMANAT	RPH88720

Staff Name:	License #:
ANN-MARIE M LEGARRETA	TCH142292
AREBELLA M VALTIERRA	TCH190310
BELINDA L BENTROTT	TCH129121
BRITTANY L SAENZ	TCH122471
CASSANDRA L HERNANDEZ	TCH[illegible]
JENNIFER L HOUSE	TCH76510
KAYLA R BROWNLEE	TCH159959
MARIE S DELGADILLO	TCH[illegible]6668
RACHELLE M MACIAS	TCH164427
SAMANTHA R STINNETT	TCH168419
SARAH K MOORE	TCH132830

Inspector Remarks:

Assisted by PIC Doherty shauna.doherty@precisionpharmacy.com (661) 377-3333
RPH Wussow, and RPH Dinh.
The designated person(s) for sterile compounding facility is PIC Doherty.
For non-sterile compounding is RPH Wussow.

Here today for a routine inspection. This is a compounding pharmacy. This is a veterinary compounding pharmacy. The pharmacy compounds mostly for equine. No human use compounding, pharmacy does compound for veterinary office use very little walk-in patients.

The pharmacy does perform non sterile compounding.

Pharmacy fills sterile and non-sterile compounded preparations: preparations with an average number of CSP's compounded daily is 2-3 times a day maximum batch 250/day.

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INSPECTION REPORT

Approximately 70% non-sterile, and 30% sterile.

ROUTINE INSPECTION:
Consultation: Pharmacy provides consultations to veterinary offices as needed and some walk-in patients. Walk in patients receive consultation on-site. Delivered products, are accompanied with literature to contact the pharmacy to speak with the pharmacist, as well as medication storage, and disposal.

QA for med errors: available, QA policy and procedures reviewed (Complaint handling SOP 5.030). Utilizing in house paper system

Reviewed QA system, written form Date of incident 11/9/2023, for RX#408527. Toltrazuril 150mg/ml in DMSO solution.

CURES: Transmitting and enrolled in PDMP

Pharmacy computer system: PK Software
RX Label: prescription labels – meets compounded sterile preparation requirements (please refer to LSC101784 inspection reports, pharmacy has new LSC 101853)

The pharmacy does sterile compounding. Please refer to LSC101784 inspection reports which have been conducted annually. (new LSC 101853)

Pharmacy records storage in pharmacy –Pharmacy paper records are stored on site.

Posted: Original pharmacy license and sterile compounding license with renewals, DEA registration, Notice to Consumer (NTC) and interpreter services.

The following were reviewed:
Pharmacy Self-Assessment- available
Sink with hot and cold running water-available for hand hygiene within LSC area as well as in the hallway area. Two sinks are also available for washing equipment, and a sink in the non-sterile compounding area.

No opioids utilized at this pharmacy, no schedule II products. Controlled substances are schedule III-V only.
Perpetual inventory utilized for all controlled substances.

They do perform quarterly of all products including controlled substances (CIII-V).

Biennial inventory last performed 4/27/2023
DEA 106-none reported
Policy and procedures reviewed for Pharmacy Technician job description, interpretive services, theft and impairment viewed. Enrolled in Board of Pharmacy subscriber alerts.
Security-only RPH's have pharmacy keypad code to alarm. Main entry has key fob access to all employees. There are 4 doors that allow entry into the pharmacy building. There are 6 doors that allow entry into the pharmacy area. The pharmacy area also has a separate alarm system.

Expired medications separated from regular stock and pulled monthly prior to two month of expired products printed expiration date. The pharmacy separates these items in bins and expired medications are quarantined and placed in a container provided by reverse distributor.

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INSPECTION REPORT

Wholesaler: Medisca, Letco, Fagron, Humco, Spectrum, PCCA, and McKesson
Reverse Distributor: Return Logistics
Pharmaceutical Waste Management: Prime medical (biohazard and expired meds), Kern County waste management (flammable, caustic), Ponder Environmental (hazardous waste)

STANDARD OPERATING PROCEDURES (USP 795) Spot checked.
Designated person identified in SOP as PIC or designee- available.
Hand hygiene and garbing -available
Monitoring of storage area temperature in SOP- available
storage of compounded preparations- available
Cleaning and sanitizing in SOP-available.
Certification of CVE annually-available performed in September 12, 13, 14, 2023 by ENV
Beyond Use Date- USP 795 (water content Aw > 0.6 preserved vs non-preserved) -available

(USP 800)
Hazardous drugs: handling/disposal, compounding, spill clean-up protocol, proper garbing (double shoe covers/gloves) – available.
Storage of API, in negative pressure area in SOP-available
ACPH >12 ACPH for storage area. Performed by ENV 9/14/2023 (45 ACPH)
Spill kits-available

(USP 797)
Monitoring of humidity- available
Aseptic technique, hand hygiene and garbing, conduct in an ISO environment -available
Facility cleaning and disinfecting- available
recalls- complaint handling, utilizing written forms-available
Environmental sampling: min weekly category 3 compounding surface sample, monthly air. Action levels for CFUs and actions to be taken when CFUs have been exceeded remediation records SOP- available.
Compounding, filling, and labeling: Beyond Use Date, storage of compounded preparations- available

Reviewed records:
Room temperature logs – viewed from October 1, 2023, through October 31, 2023
Humidity logs- viewed from October 1, 2023, through October 31, 2023.
incubator temperature logs- viewed from October 1, 2023, through October 29, 2023
refrigerator temperature logs- viewed October 1, 2023, through October 29, 2023
Pressure logs- viewed for October 1, 2023, through October 31, 2023.
Cleaning logs for room, PECs, SECS, shelving- viewed for October 1, 2023, through October 31, 2023

STERILE COMPOUNDING AREA

Designated compounding space for non-hazardous compounding and a separate designated space for hazardous compounding. The non-hazardous compounding suite consists of an ISO 8 prep room, followed by an ISO 8 garbing room, followed by an ISO 7 buffer room. The non-hazardous buffer room has two ISO 5 laminar airflow workbenches. The hazardous compounding suite consists of an ISO 8 air lock room, followed by an ISO 8 compounding room, followed by an ISO 7 ante room, followed by an ISO 7 buffer room. The hazardous buffer room has one ISO 5 biological safety cabinet. There is an ISO 8 pass-through between the hazardous ante room and the vestibule.

Last certification completed on October 25, 2023, by ENV Services for sterile non-hazardous suite and September 19-20, 2023 for

INSPECTION REPORT

hazardous suite.
Dynamic testing, HEPA filter leak testing, non-viable sampling

Air changes- for non-hazardous suite; garbing room at 48 ACPH, prep room at 42 ACPH non-hazardous buffer room 79 ACPH

For hazardous suite; airlock at 43 ACPH, prep room at 27 ACPH, garb room at 121 ACPH, hazardous buffer room 58 ACPH

Pressure differentials: for non-hazardous suite; prep room to work area at 0.038" w.c., garb room to prep room at 0.042" w.c., non-hazardous buffer room to prep room at 0.032" w.c.,

For hazardous suite; airlock to work area at 0.025"w.c., prep room to airlock at -0.024"w.c., garb room to prep room at 0.040"w.c., hazardous buffer room to garb room at -0.020"w.c.

Viable volumetric air sampling- performed date on October 25, 2023, (sterile non-hazardous suite) showed acceptable growth in ISO-7 buffer room air sample. No highly pathogenic organisms detected.

Viable volumetric air sampling- performed date on September 19, 2023, (sterile hazardous suite) showed acceptable growth in ISO-7 buffer room air sample and ISO-8 prep room. No highly pathogenic organisms detected.

Latest certification for (Sterile Hazardous Suite)
Performed November 2, 2023, by CERTS.
Dynamic testing, HEPA filter leak testing, non-viable sampling
For hazardous suite; airlock at 65.1 ACPH, prep room at 30.9 ACPH, garb room at 137.5 ACPH, hazardous buffer room 74.3 ACPH

Pressure differentials for hazardous suite; airlock to work area at 0.043"w.c., prep room to airlock at -0.032"w.c., garb room to prep room at 0.048"w.c., hazardous buffer room to garb room at -0.015"w.c.

Viable volumetric air sampling- performed date on November 2, 2023, (sterile hazardous suite) showed acceptable growth in ISO-7 buffer room air sample and ISO-8 prep room, and ISO-8 airlock surface sample. Highly pathogenic organisms detected (aspergillus) in air sample.

Remediation-report was just received today (12/6/2023). Per PIC will perform CAPA.

Investigation:

Staffing ratio- observed during inspection.
At time of inspection, observed pharmacy of staff with 6 pharmacist and 11 technicians.

Discussion:

1. Discussed CI 2023-101122 with PIC.
2. Discussed that pharmacist/technician ratios a pharmacy with only one pharmacist shall have no more than one pharmacy technician. The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1. As per 1793.7 (b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
3. Beyond use Dates (BUD) for non-sterile compounded preparations please see Table 4 (USP 795) A cream because it has a water activity (Aw) of Aw > 0.6, if it is non-preserved then it will have a BUD of 14 days. If the cream is a preserved aqueous dosage

INSPECTION REPORT

form, then it will have a BUD of 35 days, available in SOP.
4. Discussed per section 5.2 storage USP 800 API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). The pharmacy has performed ACPH for this area on September 14, 2023, by ENV. (45 ACPH)
5. Discussed that relative humidity 60% and below to minimize risk of microbial proliferation. Pharmacy has been monitoring and has SOP.
6. Remediation plans will need to be documented which the pharmacy has been performing.

Education:

1. November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.
   The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.
   During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.
   Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.
2. The October 2023 issue of The Script Newsletter is available on the Board of Pharmacy's website
3. New law changes are on the Board of Pharmacy's website under Pharmacy law changes for 2023
4. Board CE webinars and DEA training. Law & Ethics CE requirements: available on the Board of Pharmacy's website

Please provide all requested items and corrections no later than to email to: jeff.shinoda@dca.ca.gov within 14 days.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Shauna Doherty

Inspector (sign) _____

Inspector (print) JEFF SHIMODA

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

First	Last	
Lynn	Adams	
Jessica	Allred	
Paniz	Amanat	
Lauren	Angulo	
Laura	Austin	
Belinda	Bentrott	
Kayla	Brownlee	
~~Eugenia~~	~~Buoni~~	Part-time
~~Ruby~~	~~Chavez~~	Med. leave
~~Samantha~~	~~Cole~~	sick
Tammy	Conley	
Natalie	Delgadillo	
Christine	Dell'Acqua	
Phu	Dinh	
Shauna	Doherty	
Dawna	Enox	
Brenda	Gomez	
Sydney	Greene	
Mary	Habib	
~~Dena~~	~~Hattaway~~	Part-time
Cassandra	Hernandez	
~~Kelly Sue~~	~~Hotz~~	Med. leave
Jennifer	House	
~~Richard~~	~~Legarreta~~	PFL
~~Ann-Marie~~	~~Legarreta~~	Left early.
Jeff	Lodermeier	
Rachelle	Macias	
Samantha	Mahan	
Sarah	Moore	
~~Christina~~	~~Murphy~~	Part-time
~~Ashley~~	~~Nunez~~	sick
~~Ida~~	~~Osathanugrah~~	Med leave
Rosanne	Palmer	
Mayra	Portillo	
Amber	Queen	
~~Emily~~	~~Rees~~	PTO
Tessa	Roberts	
Ambar	Rodriguez	
~~Cindy~~	~~Romero~~	Part-time
Brittany	Saenz	
~~Ragini~~	~~Shah~~	Part-time
Rania	Shenoda	
Chris	Shine	
Britney	Simmer	
Samantha	Stinnett	
~~Rachel~~	~~Taggs~~	Remote

Call out 12/6/23

Ashley N.
Samantha C.
Emily Rees
Ann-Marie - Left early.

Arebella	Valtierra
Patrick	Wade
Mindy	Waite
~~Susan~~	~~Welch~~ Remote
Sara	White
~~Ashlee~~	~~White~~ Part time
Ashley	Whorf
Briant	Williams
Samra	Wussow

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101921

NAME: WEDGEWOOD PHARMACY LLC

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

5301 YOUNG ST
NON-HAZARDOUS CLN RM, HAZARDOUS CLN RMS
BAKERSFIELD CA 93311
KERN COUNTY

ISSUANCE DATE

APRIL 30, 2024

EXPIRATION DATE

APRIL 1, 2025

CURRENT DATE / TIME

NOVEMBER 20, 2024
12:40:35 PM

LICENSE RELATIONSHIPS

NAME: WEDGEWOOD PHARMACY LLC

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 59477 **PRIMARY STATUS:** CLEAR

ADDRESS :
5301 YOUNG ST
BAKERSFIELD CA 93311
KERN COUNTY

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59477

NAME: WEDGEWOOD PHARMACY LLC

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

5301 YOUNG ST
BAKERSFIELD CA 93311
KERN COUNTY

ISSUANCE DATE

APRIL 30, 2024

EXPIRATION DATE

APRIL 1, 2025

CURRENT DATE / TIME

NOVEMBER 20, 2024
12:40:39 PM

LICENSE RELATIONSHIPS

NAME: WEDGEWOOD PHARMACY LLC

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101921 **PRIMARY STATUS:** CLEAR

ADDRESS :
5301 YOUNG ST
NON-HAZARDOUS CLN RM, HAZARDOUS CLN RMS
BAKERSFIELD CA 93311
KERN COUNTY

NAME: DINH, PHU HUY

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 62659 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

Officer Information for Wedgewood Pharmacy LLC

FEIN 81-1186519

Wedgewood Pharmacy LLC will have the following three officers, none of whom are licensed pharmacists:

1. Joseph Costa

President and Chief Operating Officer
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
Home Address: [redacted] Center Valley, PA [redacted]
DOB: [redacted]
SSN [redacted]
Telephone: [redacted]
jcosta@wedgewood.com

2. Alejandro Bernal-Angel

CEO and Secretary
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
Home Address: [redacted] Haverford, PA [redacted]
DOB [redacted]
SSN [redacted]
Telephone: [redacted]
Alejandro.bernal@wedgewood.com

3. Maria Kraus

CFO
Business Address: 405 Heron Drive, Suite 200, Swedesboro, NJ 08085
Home Address: [redacted] Yardley, PA [redacted]
DOB [redacted]
SSN [redacted]
Telephone: [redacted]
Mkraus1@wedgewood.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Wedgewood Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5301 Young Street

City: Bakersfield State: CA Zip: 93311

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (661) 377-3333 Website: www.wedgewood.com

Licensing Company Email: licensing@wedgewoodpharmacy.com

Section 2: Personal Information

First: Samra Middle: Day Last: Wussow

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres[redacted]

City: Bakersfield State: CA Zip[redacted]

Telephone[redacted] Email[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A ✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		2001-2005	
Address	**City**	**State**	**Zip**
1985 Zonal Ave	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Doctorate of Pharmacy (Pharm D)			

School Name		From - To (MM/YY – MM/YY)	
California State University Bakersfield		1994-2000	
Address	**City**	**State**	**Zip**
9001 Stockdale Hwy	Bakersfield	CA	93311
Diploma/Degree obtained, if any			
Bachelor of Science in Biology, Bachelor of Science in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
South High School		08/89-05/92	
Address	**City**	**State**	**Zip**
1101 Planz Rd	Bakersfield	CA	93304
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/11-Present	[redacted]	Bakersfield	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Wedgewood Pharmacy LLC			4/2024-current	
Business Address		**City**	**State**	**Zip**
5301 Young Street		Bakersfield	CA	93311
Phone	**Title**		**Number of Employed Hours**	
(661) 377-3333	Pharmacist-in-Charge (11/2024); Compounding Supervisor		1040 hrs	

Description of Duties

Maintain and enforce policies and procedures to comply with standards of practice within current pharmacy legislation.

- •Supervise pharmacy staff
- •Perform regular audits of personnel training files.
- •inventory management, including CDS inventories
- •Knowledgeable in USP <797>,<795> and PCAB and maintain applicable standards of practice.
- •Maintain accurate records
- •Identify and recommend improvements to preparation formulas.
- •Lead quality assurance department.

Business Name			From - To (MM/YY – MM/YY)	
Precision Equine LLC			2023-2024	
Business Address		**City**	**State**	**Zip**
5301 Young Street		Bakersfield	CA	93311
Phone	**Title**		**Number of Employed Hours**	
(661) 377-3333	Nonsterile Compounding Pharmacist Supervisor		2144 hrs	

Description of Duties

Actively participate in the day-today management of the nonsterile compounding department.

- •Supervise nonsterile compounding technicians. Develop and maintain ongoing training for compounding technicians.
- •Create and review SOPs for nonsterile compounding department
- •Maintain and enforce policies and procedures to comply with SOPs, USP and current pharmacy legislation
- •Compounding formula creation and maintenance.

Business Name			From - To (MM/YY – MM/YY)	
Precision Pharmacy			2009-2022	
Business Address		**City**	**State**	**Zip**
5301 Young Street		Bakersfield	CA	93311
Phone	**Title**		**Number of Employed Hours**	
(661) 377-3333	Nonresident Pharmacist-in-Charge (VA,OR,KY,AR,KS)		23,296 hrs	

Description of Duties

Currently the Nonresident Pharmacist in Charge for the states of VA,OR,KY,AR,KS

- •Obtained pharmacist licensure by examination for states listed
- •Worked with Resident Pharmacist in Charge to maintain and enforce policies and procedures to comply with current pharmacy legislation.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Samra Day Wussow, **certify that as the designated representative for**

Wedgewood Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SW I am at least 21 years of age;
3. SW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Samra Day Wussow

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samra Day Wussow

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

Attached CA Jurat

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Kern

Subscribed and sworn to (or affirmed) before me on this 19th day of November, 2024, by Samra Day Wussow,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

(Seal) Signature

REBECCA LANE
COMM. #2410434
NOTARY PUBLIC • CALIFORNIA
KERN COUNTY
My Comm. Exp. Aug. 7, 2026

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW4366793	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	RETAIL PHARMACY	07-01-2024

WEDGEWOOD PHARMACY LLC
5301 YOUNG ST
BAKERSFIELD, CA 933118978

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW4366793	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	RETAIL PHARMACY	07-01-2024

WEDGEWOOD PHARMACY LLC
5301 YOUNG ST
BAKERSFIELD, CA 933118978

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Wedgewood Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 5301 Young Street

City: Bakersfield State: CA Zip: 93311

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 661-377-3333 Toll Free # (NAC 639.708, NRS 639.23286): 877-734-3338

Fax: 856-491-4365 Contact Email: licensing@wedgewoodpharmacy.com

Website: www.wedgewood.com

Nevada Business License # (if applicable) NV20222567471

Supervising/Managing Pharmacist Name (NRS 639.220): Samra Wussow

Supervising/Managing Pharmacist NV Pharmacist Registration #: NV RPh = Ragini Shah # 13594

Name of Designated Person(s) as defined by revised USP-797 guidelines: Phu Dinh

Email of Designated Person(s): phu.dinh@wedgewood.com

Telephone of Designated Person(s): 661-377-3333

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 9/10/24, 9/12/2024

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? N/A

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

See enclosed list for Question 11 (Section 2) and Question 1 (Section 4)

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma (ARL); Front Range Labs (FRL). Compounders International Analytical Lab (CIAL)

Address: 840 Research Pkwy#546 (ARL); 3985 S Lincoln Ave (FRL);4760 Castelon Way Suite A, Castle Rock,CO(CIAL

City: Oklahoma City (ARL); Loveland, CO 80537 (FRL) State: OK (ARL) Zip: 73104 (ARL)

Telephone: 405-271-1144 (ARL); 970-593-0171 (FRL); 303-471-8015 (CIAL)

13. What is your procedure for visual inspection of compounded sterile products?

See enclosed SOP 9.140 Sterile Compounding Finished Preparation Testing. CSP are inspected for particulate matter and container closure integrity.
In addition to the above SOP, Pharmacists, also visually inspect the sterile products at the time of dispensing.

14. How often do you perform glove fingertip and medial fill testing?

Initially and quarterly (every 3 months) for sterile compounding technicians.
Initially and annually for sterile supervising pharmacists. Initially and every six months for sterile clerks.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

See enclosed SOPs 9.130 Sterile Compounding Process Validation -Media Fills and SOP 2.030 Sterile Compounding Technician and Support Staff Qualification.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See enclosed SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities and SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection

Current agents used: TB1-3000, Peridox RTU, BruTab and Sterile Isopropyl Alcohol

17. Who performs the sterile compounding process at your facility?

Sterile technicans performed the compounding,Sterile pharmacists observe and verify the process

18. Who is responsible and accountable for the sterile compounding process at your facility?

Phu Dinh , Sterile Compounding Supervisor-Designated person for 797.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

See enclosed SOP 5.050 Shipping of Compounded Preparations

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Laminar airlflood hoods (NonHD) and Biological Safety Cabinet (HD)		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device: NA		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

See enclosed SOP 5.040
All hazardous drugs are labeled with the following statement "Hazardous dispose of properly"

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

All new and exisiting personnel are continually trained by our Hazardous Drug <USP 800> Designated Person on the hazardous drug communications program. The program promotes patient safety, worker safety, and environmental protection as described in USP 800. All pertinent staff that will handle hazardous drugs will undergo training and assessment prior to handling HD. New sterile technicians will also be trained and work closely with experienced sterile technicians on compounding and aseptic processing of Hazardous drugs.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

See enclosed list for Question 11 (Section 2) and Question 1 (Section 4)

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Quarterly (every 3 months)

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

See enclosed SOP 3.030 Environmental Monitoring of the Clean Room Facilities.

5. What is the frequency for completing surface sampling? See SOP 3.030 Environmental Monitoring of the Clean Room Facilities	
6. What is the frequency for using sporicidal agents? See SOP 3.020 Cleaning and Maintenance of the Clean room Facilities. Weekly and as needed	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component? Performed on all CSPs except Sterile Ophthalmics PER USP 797	■ Yes No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samra Wussow PharmD

Name of Person who Completed the Form

Pharmacist in Charge / Quality Manager

Title

Signature (copies or stamps not accepted)

2/3/25

Date

Board Use Only	Date Received: 2/6/25 Date Approved: _____ Approved By: _____

Question 11(Section 2) and Question 1 (Section 4)

List of Compounded Sterile Preparations compounded at our pharmacy

*** All sterile preparations are Category 3**

Adenosine-5-Monophosphate in AQ Vehicle 200mg/ml Injection Solution

Altrenogest in Propylene Glycol 225mg/ml Injection Solution

Altrenogest in Propylene Glycol 50mg/ml Injection Solution

Ammonium Sulfate in AQ Vehicle 0.75% Injection Solution

Arginine (L) in AQ Vehicle 200mg/ml Injection Solution

Atropine Sulfate in Anhydrous Lanolin 1% Ophthalmic Ointment

Calcium Chloride/Magnesium Chloride/Potassium Chloride/Sodium Acetate/Dextrose in AQ Vehicle 2.65mg/2.84mg/4.66mg/71.54mg/50mg/ml Injection Solution

Carbazochrome/Sodium Salicylate in AQ Vehicle 10mg/250mg/ml Injection Solution

Carboxymethylcellulose in AQ Vehicle 2% Irrigation Suspension

Cimetidine in AQ Vehicle 150mg/ml Injection Solution

Deslorelin (as Acetate) in AQ Vehicle 1.5mg/ml Injection Solution

Dexamethasone Phosphate (as Sodium Phosphate) in AQ Vehicle 24mg/ml Injection Solution

Estradiol 17-B in Sesame Oil 5mg/ml Injection Solution

Estradiol 17-B/Progesterone in Sesame Oil 3.33mg/50mg/ml Injection Solution

Estrone in Carboxymethylcellulose in AQ Vehicle 5mg/ml Injection Suspension

Guaifenesin in AQ Vehicle 50mg/ml Injection Solution

Guanabenz Acetate in AQ Vehicle 2mg/ml Injection Solution

Histrelin (as Acetate) in AQ Vehicle 0.5mg/ml Injection Solution

Histrelin (as Acetate) in AQ Vehicle 1mg/ml Injection Solution

Iodine in Almond Oil 2% Injection Solution

Itraconazole/DMSO in Anhydrous Lanolin 1%/27% Ophthalmic Ointment

Medetomidine HCl/Ketamine (as HCl) in AQ Vehicle 10mg/150mg/ml Injection Solution

Medetomidine HCl/Ketamine (as HCl) in AQ Vehicle 5mg/150mg/ml Injection Solution

Progesterone in Propylene Glycol 200mg/ml Injection Solution

Reserpine in AQ Vehicle 2.5mg/ml Injection Solution

Romifidine HCl in AQ Vehicle 1% Injection Solution

Stanozolol in AQ Vehicle 5mg/ml Injection Suspension

Stanozolol in AQ Vehicle 50mg/ml Injection Suspension

Tryptophan (L) in AQ Vehicle 100mg/ml Injection Solution

WEDGEWOOD PHARMACY LLC	
TITLE: STERILE COMPOUNDING FINISHED PREPARATION TESTING (END PREPARATION TESTING)	
SOP NUMBER: 9.140	**VERSION NUMBER: 17.0**
Authorized By:	Date:
Written By: PCCA / Rachel Taggs	Date: 12-7-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for finished preparation testing of sterile compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at Wedgewood Pharmacy, Bakersfield ("Bakersfield").

3.0 RESPONSIBILITY

3.1 The sterile compounding supervisor shall supervise this procedure or document that another staff member has been designated to ensure that all sterile compounding personnel responsible for finished preparation testing comply with this procedure.

3.2 It is the responsibility of the sterile compounding supervisor to review and assess the contract laboratory for appropriate regulatory compliance according to SOP 9.220 Contract Laboratory Selection and Desk Audit, or equivalent.

3.3 Testing performed in house will be performed by properly trained personnel.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <71> "Sterility Tests"

4.3 USP Current Version <85> "Bacterial Endotoxin Testing"

4.4 USP Current Version <1229.5> "Biological Indicators for Sterilization"

4.5 Applicable state board of pharmacy requirements.

4.6 SOP 6.020 Compounded Preparation Labeling, or equivalent

4.7 SOP 8.020 Biological Indicators, or equivalent

4.8 SOP 9.210 Integrity Test Method by Bubble Point, or equivalent

4.9 SOP 9.050 Determination and Extension of Beyond Use Dates (BUD) for Compounded Preparations, or equivalent

4.10 SOP 9.080 Preparation Quarantine, Storage and Release, or equivalent

4.11 SOP 9.100 Recall of Compounded Preparation, or equivalent

4.12 2023 version Law Book for Pharmacy, California

5.0 DEFINITIONS

5.1 CSP – compounded sterile preparation.

5.2 BI – biological indicator.

5.3 CI – chemical integrator.

5.4 MDV – multi-dose vial.

5.5 Filter integrity test – A test (e.g., bubble point test) of the integrity of a sterilizing grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised. (USP <797>)

6.0 FREQUENCY

6.1 It is the responsibility of the sterile compounding supervisor and/or PIC to determine when and which tests should be performed and whether tests should be conducted in-house or performed at a third party analytical/microbiological testing laboratory.

7.0 EQUIPMENT & SUPPLIES

7.1 Third party analytical/microbiological testing laboratory, if applicable.

7.2 Low-lint/Lint-free wipes.

7.3 Appropriate gloves (e.g., powder-free latex, nitrile, ASTM Tested Chemotherapy gloves).

7.4 Bubble point – filter integrity test.

7.5 Biological indicators.

7.6 Chemical integrators.

7.7 Incubators

7.8 WinKQCL Endotoxin Detection System, or equivalent.

7.9 White and black background with light.

8.0 GENERAL INFORMATION

8.1 This procedure is designed for planned testing to verify and demonstrate effectiveness of all processes and procedures critical to the accuracy and purity of the finished compounded sterile preparation.

8.2 All compounded sterile preparations are tested according to USP <797>, as applicable, and other referenced chapters.

8.2.1 USP <71> or equivalent should be followed when a sterility test is required. Within chapter <71>, the number of units, volume per unit and specific methods are discussed.

8.2.2 USP <71> ". . . Fluid Thioglycollate Medium is primarily intended for the culture of anaerobic bacteria. However, it will also detect aerobic bacteria. Soybean-Casein Digest Medium is suitable for the culture of both fungi and aerobic bacteria."

8.2.3 USP <85> "The Bacterial Endotoxins Test (BET) is a test to detect or quantify endotoxins from Gram-negative bacteria using amoebocyte lysate from the horseshoe crab (Limulus polyphemus or Tachypleus tridentatus). There are three techniques for this test: the gel-clot technique, which is based on gel formation; the turbidimetric technique, based on the development of turbidity after cleavage of an endogenous substrate; and the chromogenic technique, based on the development of color after cleavage of a synthetic peptide-chromogen complex. Proceed by any of the three techniques for the test. In the event of doubt or dispute, the final decision is made based upon the quantitative results of the test being performed on a drug in triplicate via chromogenic technique. Based upon the quantitative results the pharmacist can determine if the drug is within acceptable limits. The test is carried out in a manner that avoids endotoxin contamination."

8.2.4 <1229.5> "A biological indicator (BI) is a well-characterized preparation of a

specific microorganism that has known resistance to a specific sterilization process. BIs are used to demonstrate the effectiveness of processes that render a product sterile in its final package or container, as well as the effectiveness of the sterilization of equipment, product contact materials, and packaging components as required. BIs may also be used to monitor established sterilization cycles and are used for periodic reassessment of sterilization process effectiveness. BIs are process aids and can support the correlation of physical parameters to microbiological destruction. Microorganisms recognized as suitable for BIs are spore-forming bacteria; the spores of these microorganisms are significantly more resistant than the vegetative cells that comprise the majority of bioburden in or on materials."

8.2.5 <USP> 797 "Filter units used to sterilize CSPs must be subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters must pass a filter-integrity test.."

8.3 2023 Law Book for Pharmacy, California Title 16 of the California Code of Regulations, Article 7, Section 1751.7 Sterile Compounding Quality Assurance and Process Validation,". . . (e) (1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP <71> compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP <85> limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription."

8.4 At the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects). The CSP label must be visually inspected to confirm that the CSP and its labeling match the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).

9.0 PROCEDURE

9.1 Sterility testing.

9.1.1 Sterility testing is not required for Category 1 CSPs. For Category 2 CSPs assigned a BUD that requires sterility testing (see SOP 9.050 Determination and Extension of Beyond-Use-Dates (BUD) for Compounded Preparations, or equivalent) and all Category 3 CSPs, the testing must be performed according to USP <71> testing.

9.1.2 Sterility sampling requirements must follow the tables in USP <71>. According to California pharmacy law, all batch produced sterile drug preparations starting

with one or more non-sterile ingredients will need to undergo sterility testing unless exempted in 8.3.

9.1.2.1 The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units.

9.1.3 Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented according to SOP 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management, or equivalent.

9.1.4 Sterility methods should follow USP <71> or equivalent membrane filtration method, if applicable. If not performing membrane filtration, the methods outlined in USP <71>, or other methods proving to be equivalent or better than those methods outlined, are acceptable.

9.1.5 Communication with the laboratory will be recorded on Contract Laboratory Communication Log, Attachment 1.

9.2 Endotoxin (pyrogen) testing.

9.2.1 Category 1 injectable CSPs do not require testing for bacterial endotoxins. Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing (see SOP 9.050 Determination and Extension of Beyond-Use-Dates (BUD) for Compounded Preparations, or equivalent) and Category 3 injectable CSPs compounded from one or more nonsterile component(s) must be tested to ensure that they do not contain excessive bacterial endotoxins (see <85>). Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing should be tested for bacterial endotoxins. In the absence of a bacterial endotoxin limit in an official *USP–NF* monograph or other CSP formula source, the CSP must not exceed the endotoxin limit calculated as described in <85> for the appropriate route of administration for humans.

9.2.1 CSPs for nonhuman species must not exceed the endotoxin limit calculated as described in <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species. Calculate and document endotoxin limits according to SOP 4.270 Pyrogen Testing and Use of WinKQCL® IQ and ELx808™ OQ, Endotoxin Limit Calculations and Maximum Valid Dilution (MVD), Attachment 1, or equivalent.

9.3 Physical testing requirements.

9.3.1 At the completion of compounding, end preparation must be visually inspected to determine whether the physical appearance of the CSP is as expected, for example:

9.3.1.1 Container leaks, cracks in the container, or improper seals.

9.3.1.2 Free from inappropriate visible particulates or other foreign matter

9.3.1.3 Solution cloudiness or phase separation.

9.3.1.4 Discoloration.

9.3.1.5 Appropriate volume.

9.3.1.6 Or other defects.

9.3.2 Particulate testing.

9.3.2.1 Compounded sterile preparation solutions shall be checked when being placed into quarantine and individually checked prior to dispensing.

9.3.2.1.1 Wipe the container with a damp, lint-free wipe to remove any external particles.

9.3.2.1.2 Hold the container by its top and swirl the contents by rotating the wrist in a circular motion.

9.3.2.1.3 Hold the container horizontally about four inches below a light source against a white and/or black background and move the container back and forth.

9.3.2.1.4 Slowly invert the container and look for heavy particles that may have settled on the bottom of the container.

9.3.2.2 Bottles containing visible particulate matter must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal according to SOP 9.090 Proper Disposal of Pharmacy Waste, or equivalent.

9.4 Accuracy requirements.

9.4.1 Final check of preparation must be performed by a sterile compounding pharmacist.

9.4.2 Accuracy must meet applicable state board requirements.

9.4.3 All preparation weights and volumes must be verified by a sterile compounding pharmacist.

9.4.4 All calculations and volumes must be verified on the batch by a sterile compounding pharmacist.

9.5 Identification and potency requirements.

9.5.1 Verify the label has the correct:

9.5.1.1 Names.

9.5.1.2 Amounts or concentrations of ingredients.

9.5.1.3 Total volume.

9.5.1.4 Beyond-use date.

9.5.1.5 Appropriate route(s) of administration.

9.5.1.6 Storage conditions.

9.5.1.7 Other safe use information as needed.

9.5.2 Verify the compounding record to the original written order for correct identities of ingredients and amounts of ingredients. If any of these cannot be confirmed, the preparation must be reviewed by a sterile compounding pharmacist and appropriate action must be taken, following all necessary and appropriate policies, if applicable.

9.5.3 Verify that correct fill volumes and quantities of units were prepared.

9.5.4 At the discretion of a sterile compounding pharmacist on duty, samples shall be tested for potency using the appropriate method by sending to a contract lab for testing.

9.6 If a pH requirement exists, test pH according to SOP 4.360 Use, Calibration and Maintenance of the pH Meters during the compounding process, or equivalent.

9.7 All autoclaved preparations will include biological indicators and chemical integrators. Results will be documented on appropriate forms as indicated in SOP 8.020 Biological Indicators, or equivalent.

9.8 All preparations sterilized in the dry-heat oven will include biological indicators. Results will be documented on appropriate forms as indicated in SOP 4.380 Use Verification and Maintenance of the Thermo Scientific-Heratherm Dry-Heat Oven, or equivalent.

9.9 All filters used for sterilization by filtration will be integrity tested per SOP 9.210 Integrity Test Method by Bubble Point, or equivalent.

9.9.1 If a filter is lost before it can be tested, the batch must be disposed of according to SOP 9.090 Proper Disposal of Pharmacy Waste, or equivalent, and an OOS must be completed.

9.10 An aqueous multiple-dose CSP must additionally pass antimicrobial effectiveness testing in accordance with USP <797> and <51> Antimicrobial Effectiveness Testing.

9.11 Sterile preparations will not be dispensed until all applicable end preparation testing is complete. Once testing is complete a sterile compounding pharmacist will release the preparation according to SOP 9.080 Preparation Quarantine, Storage and Release, or equivalent.

9.12 If any of the finished preparation testing is out of specification or unacceptable quality (e.g., observed defects), the preparation must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before an investigation can be performed, according to applicable SOPs. The investigation should determine the cause and if a preparation recall is necessary.

10.0 ATTACHMENTS

10.1 Attachment 1 – Contract Laboratory Communication Log

11.0 HISTORY

Version Number	Review Date	Effective Date	Description of Change
1.0	10-2009-12/2009	1-1-2010	New SOP
2.0	12-28-2010	1-1-2011	Annual Review; procedural changes
2.0	12-28-2010	1-1-2011	Annual Review; No Changes
Version Number	**Review Date**	**Effective Date**	**Description of Change**
3.0	1/2013-6/2013	6-14-2013	Annual Review; procedural changes (see draft in file for specifics)
4.0	2-14-14	2-17-14	Annual Review; procedural changes (USP) (see draft in file for specifics)
5.0	2-19-2014	3-17-2014	See draft in file for specific changes

6.0	6-10-2014	6-12-2014	See draft in file for specific changes
7.0	9-2-2014	9-4-2014	Added Attachment 3
8.0	10-10-14	10-10-2014	Added 9.1.6, 9.1.7 and Attachment 4
9.0	3-27-2015	5-5-15	Annual Review; Grammar; Added 9.8, renumbered 9.9 and 9.10; Updated Attachment 4
10.0	7-26-2016	9-13-2016	Annual Review; Updated 7.3, 9.1.7, 9.2.4, 9.3.2.3, 9.4.2, 9.6, 9.11; Added 9.10; Updated Attachments, removed reference to Rapid
11.0	8-10-2017	8-29-2017	Annual Review; Updated 3.1, 9.3.2.6, 9.8 and grammar/language (non-procedural) throughout; Added 8.3
12.0	8-14-2018	11-2-2018	Annual Review; Updated 9.3.2.1, Attachment 3, 4; Added 9.7.1, 9.7.2, 9.7.2, 9.8.1, 9.9.1; Removed 9.4.5; Grammar and formatting throughout
13.0	1-17-2020	2-3-2020	Annual Review; Added 4.12, 9.1.8; Removed references of "product" replaced with "preparation"; Removed Attachment 2, replaced with CAPA attachment in SOP 1.030; Updated 9.3.2.2; Minor grammar throughout
14.0	8-14-2020	10-6-2020	Annual Review; Updated 4.2, 4.4, 8.2.4, 9.1 and 9.1.7; Added 5.4 and 9.1.3.5.1; Grammar/formatting throughout
15.0	12-7-2021	1-10-2022	Annual Review; Updated 6.1, 9.1.1 – 9.1.3.3, 9.1.4, 9.5.4 and Attachment 2; Removed 9.1.3.5.1, 9.1.7 (renumbered) and Attachment 3; Grammar/formatting throughout
16.0	12-9-2022	2-16-2023	Annual Review; Updated Precision Pharmacy to Precision Equine (Precision) throughout; Updated 9.4.1, 9.4.3, 9.4.4, 9.5.2, 9.10 and Attachment 2; Grammar/formatting
17.0	10-25-2023 7-23-2024	9-11-2024	Annual Review; Updated for USP <797> effective 11-1-2023; Updated 3.2, 6.1, 7.2, 8.2.2, 8.2.5, 9.1.1 - 9.1.3, 9.2.1, 9.2.2, 9.3.1-9.3.1.6, 9.3.2.2, 9.8, 9.9.1, 9.11; Added 5.5, 8.4 and 9.120; Removed 9.7.1 – 9.7.3, 9.8.1 and 9.9.2 (exceptions that allowed batch to proceed with RPh professional judgement without BI, CI or if filer was lost); Updated Precision Equine to Wedgewood Pharmacy/Bakersfield throughout; Removed Sterility Testing Log, Attachment 1

The remainder of this page intentionally left blank.

Contract Laboratory Communication Log

Form Completed by: **Date:**

Preparation Name :
Lot Number:
Contract Lab:
Type of Test (Sterility/Pyrogen):

Possible information to include: what method was used (filtration/direct inoculation), when turbidity occurred, microbial identification, lab environmental monitoring, cleaning, etc.
Contact at lab:
Test Method:
Microbial ID:
Explanation of issue:

Initials: _____

Contract Laboratory Communication Log

Reviewed by: _____ Date: _____
(Pharmacist)

WEDGEWOOD PHARMACY LLC	
TITLE: STERILE COMPOUNDING PROCESS VALIDATION (MEDIA FILLS)	
SOP NUMBER: 9.130	**VERSION NUMBER: 20.0**
Authorized By:	Date:
Written By: Taggs/Shine Hernandez/Doherty	Date: 4-8-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for sterile compounding process validations (media fills) in accordance with USP <797>.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at Wedgewood Pharmacy, Bakersfield ("Bakersfield").

3.0 RESPONSIBILITY

3.1 The Sterile Compounding Pharmacist Supervisor shall supervise this procedure and document that all sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 2.030 Sterile Compounding Technician and Support Staff Qualification (Attachments 2 and 3), or equivalent

4.3 SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent

4.4 SOP 3.030 Environmental Monitoring of the Clean Room Facilities, or equivalent

4.5 SOP 1.030 Deviation – OOS and Corrective and Preventative Action (CAPA) Management, or equivalent

4.6 SOP 4.260 Use and Maintenance of the Dwyer Mark II Manometer, or equivalent

4.7 2024 Law Book for Pharmacy; California; California Code of Regulations, Title 16 Division 17 Article 4.5 Section 1735.1 Compounding Definitions

4.8 California Board of Pharmacy Compounding Policy Statement

5.0 DEFINITIONS

5.1 Aseptic technique – a set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum (USP <797>).

5.2 Aseptic processing – a method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration or by autoclave) (USP <797>).

5.3 Aseptic processing area – controlled environment for sterile compounding; consists of several zones in which the air supply, materials, equipment, and personnel are regulated to control microbial and particulate contamination to acceptable levels (PCCA).

5.4 Direct compounding area (DCA) – A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air (USP

<797>).

5.5 First air – The air exiting the HEPA filter in a unidirectional air stream (USP 797).

5.6 Media fill test - a simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination (USP <797>).

5.7 CSP – compounded sterile preparation.

5.8 TSB – tryptic soy broth

5.9 TSA – tryptic soy agar

5.10 SDA – sabouraud dextrose agar

5.11 MEA – malt extract agar (may be used when SDA is unavailable).

5.12 PPE – personal protective equipment

5.13 HEPA – high-efficiency particulate air.

5.14 PEC – primary engineering control

5.15 IPA – isopropyl alcohol

6.0 FREQUENCY

6.1 For high-risk compounding or Category Three CSPs, sterile compounding personnel must each complete an initial media fill before performing sterile compounding or supervising sterile compounding.

6.1.1 For personnel compounding Category Three CSPs, the aseptic manipulation competency (media fill) must occur initially and at least every three months thereafter (USP 797).

6.1.2 Personnel who have direct oversight of sterile compounding personnel must complete a media fill annually. Media fills should correspond to the type of activities of the personnel they oversee but does not require the same quantities (USP 797).

6.2 When the quality assurance program yields an unacceptable result.

6.3 When a change occurs that would impact the aseptic process or when improper aseptic techniques are observed.

7.0 EQUIPMENT & SUPPLIES

7.1 ISO Class 5 (Class 100) or better air

7.2 ISO Class 7 (class 10,000) or better air

7.3 ISO Class 8 (class 100,000) or better air

7.4 Incubator

7.5 Repeater pump

7.6 Laminar airflow workbench/Biological safety cabinet class II

7.7 Scales

7.8 Powder containment hood/Biological safety cabinet class I

7.9 PPE

7.10 For specific media fill supplies, see batch ticket.

8.0 GENERAL INFORMATION

8.1 Media fills must be conducted without interruption.

8.2 Media fills shall be performed under the most challenging or stressful conditions encountered during compounding.

8.3 Separate tests will be performed with prepared TSB. Two positive controls should also be created with the media. These tests should mimic the process of filtration that is most commonly used along with the largest batch volumes each person can filter in a single work shift.

8.4 Media fill procedures mimic making a high-risk/Category Three sterile compounded preparation where non-sterile media is filtered to produce sterile media.

8.5 Media fill turbidity observation will be performed in-house.

Note: In instances where USP and California Board of Pharmacy regulations are in conflict or where current regulations are under board of pharmacy review (e.g., CA BOP reviewing current 2023 compounding regulations in preparation for new USP effective November 1, 2023), Bakersfield will make every effort to follow the strictest rule, regulation, or guideline.

9.0 PROCEDURE

9.1 Media fill procedures.

9.1.1 Growth promotion of media may be done concurrently with the media fill and verified after the media fill run (certificate of analysis indicating vendor growth promotion is acceptable).

9.1.1.1 The incubation temperature will be the same as that used for the media filled units.

9.1.1.2 The medium selected must be capable of growing a wide spectrum of microorganisms and of supporting microbiological recovery and growth of low numbers of microorganisms.

9.1.2 Positive control

9.1.2.1 There shall be two positive controls of media created for each batch ticket.

9.1.3 High-risk/Category Three media fills – non-hazardous and hazardous.

9.1.3.1 All media fills shall be conducted using the current batch ticket utilizing proper aseptic technique according to SOP 1.060 General Aseptic Technique, or equivalent.

9.1.3.2 Media fills shall be conducted in clean room facilities and engineering controls according to SOP 3.010 Sterile Compounding Area Requirements, or equivalent.

9.1.3.3 In an ISO 8 preparation area, dissolve non-sterile TSB granules in sterile water to make a 3% solution.

9.1.3.4 Components should be assembled and brought into the ISO Class 7 buffer room.

9.1.3.5 Disinfect the PEC in accordance with SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities and/or 13.020 Deactivation, Decontamination, Cleaning and Disinfection, or equivalent.

9.1.3.6 Disinfect each component prior to placing in the PEC.

9.1.3.7 Work at least six inches within the PEC to protect the critical sites from

contamination and not interrupt first air.

9.2 Incubation and inspection of media-filled units.

9.2.1 Leaking or damaged media fill units must be removed. Document the quantity removed and the reason for removal on Qualification of Personnel (Media Fills) – Sterile Compounding, Attachment 1, or equivalent, and on the Daily Monitoring Record, SOP 3.030 Environmental Monitoring of the Clean Room Facilities, Attachment 2, or equivalent.

9.2.2 All media fill units and positive control media units shall be incubated at 20°C – 25°C and 30°C – 35°C for a minimum of seven days at each temperature band to detect a broad spectrum of microorganisms.

9.2.3 All media fill units shall be stored and manipulated to allow contact of the media with all product contact surfaces in the unit.

9.2.4 Media shall be visually inspected daily for the presence of visible turbidity or other visual manifestations of growth indicating a media failure. Document daily inspection on SOP 3.030 Environmental Monitoring of the Clean Room Facilities, EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent.

9.3 Contamination with media.

9.3.1 Contamination of the area and equipment with media during media-fill processing shall not compromise the quality of the facility and equipment or the preparation subsequently processed using the same facility and equipment.

9.3.2 Media spills must be handled properly and promptly by cleaning and disinfecting the facility and equipment according to applicable SOPs (e.g., 7.030 API, Compounded Preparation and Biohazardous Spills, or equivalent).

9.4 Documentation requirements for media fills shall be recorded on Qualification of Personnel – Sterile Compounding form, Attachment 1, or equivalent, the batch ticket or according to SOP 3.030 Environmental Monitoring of the Clean Room Facilities, EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent.

9.4.1 Documentation shall include, and not be limited to, the following items:

9.4.1.1 Name of the person evaluated/conducting the media fill.

9.4.1.2 Date, time, and location of media fill (*Example Laminar Air Flow Hood number 2).*

9.4.1.3 Components used (e.g., tubing, filter, etc.) to include manufacturer or supplier, lot numbers, expiration date and size.

9.4.1.4 Volume filled and filling speed.

9.4.1.5 Type of media used, manufacturer or supplier, lot number, expiration date and growth promotion date/results (if purchased, a certificate of growth promotion should be maintained on file).

9.4.1.6 Number of units filled.

9.4.1.7 Number of units rejected at inspection and reason for rejection.

9.4.1.8 Number of units incubated.

9.4.1.9 Incubation date, time, temperature. Including incubation start times and temperature intervals.

9.4.1.10 Name(s) or other identification of the observer and the person who reads and documents the results.

9.4.1.11 Number of positive units at the conclusion of the incubation.

9.4.1.12 Results (pass/fail).

9.5 Garbing and cleaning assessments.

9.5.1 Along with the media fill procedure, personnel will be assessed and observed on hand hygiene, garbing, and cleaning competency.

9.5.2 Observations will be recorded by a pharmacist using Aseptic Technique and Related Practices of Compounding Personnel and Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel/Cleaning Assessment, Attachment 2, or equivalent.

9.5.3 An initial glove test for both hands (fingers and thumbs) will be performed immediately after garbing before spraying hands with IPA. Additionally, gloves test and surface samples of the PEC shall be collected immediately following the media fill test, prior to disinfecting gloves and PEC.

9.5.4 Record the number of cfu per hand (left hand, right hand).

9.6 Personnel and environmental monitoring (EM).

9.6.1 Settling plates.

9.6.1.1 The compounder shall place one TSA settling plate within the PEC for a maximum time of four hours per sub test. This is used as a dynamic condition environmental test.

9.6.2 Glove tests.

9.6.2.1 The compounder shall take glove samples of his or her finger and thumb tips to monitor aseptic technique. Glove tests are to be done at the completion of each media fill sub test prior to disinfecting gloves. The compounder shall roll each gloved fingertip, to include thumbs, to the agar surface, making certain to not re-touch areas. The compounder will test each hand on a separate TSA sampling plate.

9.6.1.2 Gloves must be changed prior to continuing the media fill after touching the agar surface.

9.6.3 Surface sampling.

9.6.3.1 Surface sampling of the direct compounding area must be done at the conclusion of the media fill.

9.6.4 There shall be one positive control contact plate for each lot number of media used. Touch the agar surface with an un-gloved fingertip replace the lid, label the plate appropriately and incubate according to step 9.7.

9.6.5 There shall be one negative control contact plate for each lot number of media used. Label an unopened plate appropriately and incubate according to step 9.7.

9.6.6 For glove tests, record the number of cfu per hand (left hand, right hand).

9.6.7 For environmental monitoring plates, record the number of cfu per sample location.

9.7 In-house incubation of environmental controls and samples.

9.7.1 All TSA plates shall be incubated at 30°C – 35°C for no less than 48 hours and then at 20°C – 25°C for no less than 5 additional days.

9.7.2 Plates shall be checked daily for growth and results documented on SOP 3.030 Environmental Monitoring of the Clean Room Facilities, EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent.

9.8 Acceptance criteria.

9.8.1 All media must demonstrate growth promotion capabilities.

9.8.1.1 If no growth is observed in the positive control containers, repeat the growth promotion study with new components. Incubate the samples at the appropriate temperature with a negative control for seven days or until growth is observed. If no growth is observed, the medium is unacceptable for use, and the results of the media fill are invalid.

9.8.1.2 A certificate of analysis indicating vendor growth promotion is acceptable.

9.8.2 Calibration documentation of all equipment must be current and verified.

9.8.3 Sterile compounding facilities must meet the requirements outlined in SOP 3.010 Sterile Compounding Area Requirements, or equivalent.

9.8.4 All media fill units must be clear, free of turbidity. Failure is indicated by visual turbidity or other visual manifestations of growth in the media in one or more containers on or before the end of the incubation period.

9.8.5 For glove tests, determine whether the cfu action level is exceeded by counting the total number of cfu from both hands. Action levels are outlined in SOP 3.030 Environmental Monitoring of the Clean Room Facilities, USP Action Levels for Air, Surface, Gloves and Garb Monitoring, Attachment 4, or equivalent. Failure of the media fill assessment is indicated if glove tests meet or exceed action levels.

9.8.6 All in-house environmental data must be recorded, and all results must be within acceptable levels, according to SOP 3.030 Environmental Monitoring of the Clean Room Facilities, or equivalent.

9.8.7 Environmental samples taken in the PEC shall be evaluated and growth shall be identified to at least the genus level when action levels are exceeded regardless of the outcome of the media fill.

9.8.8 All media fill failures must have a formal investigation completed. (SOP 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management, Attachment 3), or equivalent.

9.8.9 A summary report (Validation of Personnel - Sterile Compounding, SOP 2.030 Sterile Compounding Technician and Support Staff Qualification, Attachment 2, or equivalent), along with Attachments 1 and 2, or equivalent, shall be generated for each media fill.

9.8.10 A failure in the media fill, gloved fingertip and thumb sampling or surface sample constitutes an overall failure of the aseptic manipulation competency.

10.0 ATTACHMENTS

10.1 Attachment 1 – Qualification of Personnel (Media Fills) – Sterile Compounding

10.2 Attachment 2 – Aseptic Technique and Related Practices of Compounding Personnel and Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel/Cleaning Assessment (Page 1 and Page 2)

11.0 HISTORY

TITLE: STERILE COMPOUNDING PROCESS VALIDATION (MEDIA FILLS)	
SOP NUMBER: 9.130	**VERSION NUMBER: 20.0**
Date Effective:	

Version Number	Review Date	Effective Date	Description of Change
1.0	10/2009 - 12/2009	1-1-2010	New SOP
1.0	12-28-2009	1-1-2010	Annual Review; No changes
2.0	7-15-2011	7-15-2011	Annual Review; See hard copy for specific changes
2.0	12-20-2011	7-15-2011	Annual Review; No Changes
2.0	1/2013-6/2013	7-15-2011	Annual Review; No Changes
3.0	12-1-2013	12-1-2013	Annual Review; See hardcopy for specific changes
4.0	5-1-2014	8-21-2014	See hardcopy for specific changes
5.0	3-4-2015	6-5-2015	Annual Review; Updated procedures; Added Attachments; See hardcopy for specific changes
6.0	9-1-2015	9-4-2015	Removed Part D. Compounding technique no longer used
7.0	6-30-2016	7-19-2016	Annual Review; extensive see hard copy for specific changes
8.0	12-9-2016	12-28-2016	Annual Review; Updated 5.5, 7.9, 9.1.3.4, 9.1.3.5, 9.1.3.8, 9.8.6, Attachments 1 and 2; Added 4.7, 6.2, 6.3, 8.4, 9.5.3; See hardcopy for specific changes
9.0	1-25-2017	3-9-2017	Updated 6.3, Attachment 1 and minimal process updates
10.0	9-11-2017	9-13-2017	Updated Attachment 1 (removed Test D)
11.0	12-8-2017	1-12-2018	Annual Review; Updated "product" and "preparation" throughout; Updated 5.4, 5.10, 5.11, Section 7.0, 9.1.3.3, 9.1.3.8, 9.2.1, 9.4.1, 9.6.1.1, 9.6.2, 9.6.3, 9.8.9 and Attachments; Added 5.5; Grammar/language throughout
12.0	2-15-2019	4-26-2019	Annual Review; Added 5.11; Updated 6.1, 6.3, 8.3, 9.1.3.1, 9.1.3.3, 9.1.3.5, 9.2.3, 9.3.2, 9.6.1, 9.6.1.1 and 9.8.9; Updated Attachments 1 and 2 (page 1); Grammar/formatting throughout
13.0	3-16-2020	4-27-2020	Annual Review; Updated 4.5, 4.7, 5.2, 9.1.3.1, 9.1.3.3, 9.1.3.6-9.1.3.8, 9.2.1, 9.3.1, 9.3.2, 9.6.1.1, 9.8.4-9.8.8 and Attachment 2, page 1; Removed 9.8.3 and 9.8.4 and reformatted section; Added 5.12-5.15; Grammar/formatting throughout
14.0	4-8-2021	7-16-2021	Annual Review; Updated 5.14, 6.1, 9.1.3.8, 9.3.2, 9.8.8 and Attachment 2, page, 1; Grammar/formatting throughout
15.0	9-30-2022	1-11-2023	Annual Review; Updated Precision Pharmacy to Precision Equine (Precision) throughout; Updated 6.1, and 9.2.4; Grammar/formatting
16.0	9-22-2023	10-11-2023	Annual Review; Updated for new USP effective 11-1-2023: See hardcopy and electronic files for specifics
17.0	10-23-2023	10-26-2023	Updated garbing order on Attachment 2 page 2
Version Number	**Review Date**	**Effective Date**	**Description of Change**
18.0	9-19-2024	10-29-2024	Annual Review; Updated Precision Equine to Wedgewood Pharmacy throughout; Updated "designated person" to Sterile Compounding Pharmacist Supervisor

			throughout; Updated LFW terminology to batch ticket; Added "or equivalent" to Bakersfield SOPs to allow for integration
19.0	1-7-2025	1-14-2025	Updated 9.8.7 to make clear that samples are sent for genus level identification only when action levels are exceeded. Updated 9.6.2.1 to reflect correct process for glove fingertip and thumb sampling (roll rather than touch plate).
20.0	1-29-2025		Updated Attachment 2 to reflect new garbing order for new sterile face mask. Hair cover is now donned before the mask and removed after the face mask.

Remainder of this page intentionally left blank.

QUALIFICATION OF PERSONNEL (MEDIA FILL) – STERILE COMPOUNDING

Personnel involved in preparing drug compounds shall be evaluated for proper technique and understanding of the concepts behind the procedures to be performed. Qualification shall be handled under a "pass/fail" grading system. If the individual performing the procedure does not "pass" then proper retraining and education shall be given and the individual shall not be allowed to perform the procedure again until competency is demonstrated.

Date: _____ **Location:** _____

Employee Name: _____ **Supervising RPh:** _____

Media Fill Test (Filtration Process)

Media Used	Mfg	Lot Number	Expiration Date

Test:	Vial Size	Media Qty	Qty	Results	Initials
A				□ P □ F	
B				□ P □ F	
C				□ P □ F	

Media Fill - Positive Control

_____ml Non-Sterile Media: _____ Initial **Positive Reaction:** _____

_____ml Sterile Media w/ ____ml Non-Sterile Media: _____ Initial **Positive Reaction:** _____

Media Fill - Test A

Filter: _____ **Lot/Exp:** _____ **Bubble Point:** _____

Media Fill - Test B

Filter: _____ **Lot/Exp:** _____ **Bubble Point:** _____

Media Fill - Test C

Filter: _____ **Lot/Exp:** _____ **Bubble Point:** _____

Media Fill – Glove Tests

Media Used	Mfg	Lot Number	Expiration Date

Initial Glove Test Before Media Fill: _____ **CFU Count**

Test # A: CFU Count_____ **Test # B: CFU Count**_____ **Test # C: CFU Count**_____

Results: □ P □ F

Surface Sampling

Media Used	Mfg	Lot Number	Expiration Date

_____ **CFU Count Results:** □ P □ F

Performed By: _____ **Date:** _____

Reviewed By: _____ **Date:** _____

Room being assessed:
☐ Non-Hazardous Clean Room
☐ Hazardous Clean Room

Aseptic Technique and Related Practices of Compounding Personnel (Media Fill)

Aseptic Technique, Safety, and Quality Assurance Practices:

_____ Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.

_____ Disinfects ISO Class 5 surfaces with an appropriate agent(s).

_____ Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.

_____ Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.

_____ Does not interrupt, impede, or divert flow of first air to critical sites.

_____ Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.

_____ Performs manipulations only in the appropriate direct compounding area of the ISO Class 5 device.

_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air.

_____ Labels preparation(s) correctly.

_____ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.

_____ Disposes of waste according to SOPs.

Cleaning Practices During Media Fill:

_____ Uses disinfectant prepared at correct concentration according to SOP(s) and manufacturer's instructions.

_____ Uses appropriately labeled solution for the type of surface being cleaned (ISO 5, work surfaces, floors, etc.).

_____ At the beginning of each shift, cleans all ISO 5 surfaces prior to compounding in the following order: ceiling, walls, IV bar (if applicable) and work surface.

_____ Uses a lint free ISO 5 wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to completely dry.

_____ Removes all compounding components and cleans all ISO Class 5 areas at the end of the shift.

_____ Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

RESULTS	CFU COUNT/ ABSENCE OF TURBIDITY	PASS	FAIL	OOS (If marked, see appropriate OOS form)	Initials
GLOVE					
DCA SURFACE SAMPLE					
FILTERED MEDIA					

Printed Name of Person Assessed: _____

Signature of Person Assessed: _____ **Date:** _____

Signature of Pharmacist: _____ **Date:** _____

Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel

Hand Hygiene and Garbing Practices: A qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

Room being assessed:
☐ Non-Hazardous Clean Room
☐ Hazardous Clean Room

_____ Presents in a clean appropriate attire and manner.
_____ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
_____ Brings no food or drinks into or stored in the ante-areas or buffer areas.
_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
_____ Dons beard cover, if necessary.
_____ Dons head cover assuring that all hair is covered.
_____ Dons face mask to cover bridge of nose down to include chin.
_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds (procedure performed in prep room).
_____ Dries hands and forearms using lint-free towel (procedure performed in prep room).
_____ Pushes door leading from prep room to garb room open without touching clean hands.
_____ Dons shoe covers one at a time, placing the covered on clean side of the line of demarcation, as appropriate.
_____ Disinfects hands using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry.
_____ Dons first pair of gloves.
_____ Dons a sterile hood by grasping the edges and pulling over the head. Ensure hair cover remains in place.
_____ Selects the appropriate sized coverall, examining for any holes, tears, or other defects.
_____ Dons coverall and ensures full closure.
_____ Dons sterile disposable HD gown over coveralls, if in hazardous room.
_____ Dons a pair of sterilized eye protection. Must be worn in a manner to completely cover eyelashes, eyebrows, and exposed skin not covered by the hood.
_____ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity.
_____ Ensures there is no exposed skin inside the Buffer room for Category 3 CSPs.
_____ Pushes door from garb room to buffer room open without touching gloves.
_____ Once inside the buffer room, aseptically don a second pair of sterile gloves ensuring there is a tight fit with no excess glove material at the fingertips. Examine for defects, holes, or tears.
_____ Sprays gloves with sterile 70% IPA and allows to air dry before compounding.
_____ While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
_____ Removes gloves and performs hand hygiene (surgical hand scrub).
_____ Removes gown/coverall and discards.
_____ Removes eye protection, hood, mask, beard cover (if used), head cover, first pair of gloves.
_____ PPE was removed on the clean side of the garb room.
_____ Removes shoe covers one at a time, ensuring that uncovered designated shoe is placed on the dirty side of the line of demarcation (Removes shoe covers every time the compounding area is exited).
_____ Performs hand hygiene again (procedure performed in prep room).

*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.

RESULTS	CFU COUNT	PASS	FAIL	OOS	Initials
GLOVE TEST PRIOR TO MEDIA FILL					

Printed Name of Person Assessed: _____

Signature of Person Assessed: _____ Date: _____

Signature of Pharmacist: _____ Date: _____

WEDGEWOOD PHARMACY LLC	
TITLE: STERILE COMPOUNDING TECHNICIAN AND SUPPORT STAFF QUALIFICATION	
SOP NUMBER: 2.030	**VERSION NUMBER: 23.0**
Authorized By:	Date:
Written By: PCCA/Taggs/Shine	Date: 6-14-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 Wedgewood Pharmacy, Bakersfield ("Bakersfield") shall require basic qualifications for each employee actively involved in sterile compounding.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel in Bakersfield to include both hazardous and non-hazardous sterile compounding.

3.0 RESPONSIBILITY

3.1 The Sterile Compounding Pharmacist Supervisor shall supervise this procedure or document that another staff member has been designated to complete this task.

3.2 Each pharmacist and technician shall be responsible for ensuring their professional license is kept current and in good standing.

4.0 REFERENCES

4.1 2024 Law Book for Pharmacy, California; Sections 1751.3 Sterile Compounding Policies and Procedures, 1751.6 Sterile Compounding Consultation; Training of Sterile Compounding Staff and 1751.7 Sterile Compounding Quality Assurance and Process Validation

4.2 Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter G, Rule §291.133- Pharmacies Compounding Sterile Preparations

4.3 Current version USP <797> "Pharmaceutical Compounding – Sterile Preparations"

4.4 Current version USP <800> "Hazardous Drugs – Handling in Healthcare Settings"

4.5 SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent

4.6 SOP 9.110 Proper Hand Washing Procedure, or equivalent

4.7 SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent

4.8 SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent

4.9 ACHC PCAB November 2023 Standard TCRX5-G Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.

5.0 DEFINITIONS

5.1 ACPE – Accreditation Council for Pharmacy Education

5.2 CFU – colony forming units

5.3 CSP – compounded sterile preparation

6.0 FREQUENCY

6.1 Commencement of employment or initial training before performing sterile compounding.

6.2 For personnel compounding Category Three CSPs, the aseptic manipulation competency (media fill) shall occur initially and at least every three months thereafter.

6.3 Additionally, before beginning to compound CSPs independently personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. This must be completed initially and at least every 12 months in at least the areas described in 8.1.4 below.

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 Initial sterile technician training (Texas Administrative Code- Rule §291.133, CCR 1751.6(e) and USP <797>).

8.1.1 Initial training must be obtained through completion of either:

8.1.1.1 A single course, a minimum of 40 hours of instruction and experience. Such training shall be obtained through completion of a course sponsored by an ACPE-accredited provider; or

8.1.1.2 A training program which is accredited by the American Society of Health-System Pharmacists.

8.1.2 Complete a structured on-the-job didactic and experiential training program in Bakersfield which provides sufficient hours of instruction and experience in the facility's sterile compounding processes and procedures.

8.1.3 The experiential portion of the training program must be supervised by a trained sterile compounding pharmacist as outlined in SOP 2.060 Compounding Pharmacist Qualification, or equivalent.

8.1.4 The didactic and experiential training shall include instruction, experience and demonstrated proficiency in the following areas:

8.1.4.1 Aseptic technique (CCR 1751.6 (e), TAC §291.133 and <797>).

8.1.4.2 Critical area contamination factors (TAC §291.133).

8.1.4.3 Environmental monitoring (TAC §291.133).

8.1.4.4 Structure and engineering controls related to facilities (TAC §291.133).

8.1.4.5 Container, equipment and closure system selection/equipment and supplies, to include their proper use (CCR 1751.6 (e), TAC §291.133 and <797>).

8.1.4.6 Pharmaceutical calculations and terminology/sterile preparation calculations and terminology (CCR 1751.6 (e) and TAC §291.133).

8.1.4.7 Sterile preparation compounding documentation (e.g., master formulas and batch tickets) (CCR 1751.6 (e), TAC §291.133 and <797>).

8.1.4.8 Quality assurance procedures (CCR 1751.6 (e) and TAC §291.133).

8.1.4.9 Aseptic preparation procedures (CCR 1751.6 (e) and TAC §291.133).

8.1.4.10 Proper hand hygiene, gowning/garbing and gloving technique (CCR 1751.6 (e), TAC §291.133 and <797>).

8.1.4.11 Cleaning, disinfecting, sanitizing, and maintaining of equipment in the controlled area/Cleaning procedures including decontamination (where applicable) (CCR 1751.3, CCR 1751.6 (e) and TAC §291.133).

8.1.4.12 General conduct in the controlled area to include principles of movement of materials and personnel within the compounding area (CCR 1751.6 (e),TAC §291.133 and <797>).

8.1.4.13 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients; including achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) (CCR 1751.6 (e) and <797>).

8.1.4.14 Measuring and mixing (<797>).

8.1.4.15 Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area (<797>).

8.1.4.16 Proper use of PECs (<797>).

8.1.5 Each sterile compounding technician must successfully complete an initial glove/garbing competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before compounding.

8.1.6 Each sterile compounding technician must successfully complete an initial media fill test before compounding to demonstrate competency in aseptic technique.

8.2 Initial hazardous sterile technician training, if applicable.

8.2.1 A sterile compounding technician must complete all the requirements outlined in 8.1 before becoming trained in hazardous sterile compounding.

8.2.2 Be trained and demonstrate competence in the safe handling and compounding of hazardous agents (CCR 1751.6).

8.2.2.1 To include, and may not be limited to, items addressed in SOPs 13.010 Hazardous Communication Program and 13.020 Deactivation, Decontamination, Cleaning and Disinfection, or equivalent.

8.2.3 Complete an initial media fill in the hazardous clean room to demonstrate competency in aseptic technique.

8.3 Ongoing sterile technician training.

8.3.1 After initial training is complete, each sterile compounding technician must successfully complete a media fill test, glove/garb assessment and cleaning assessment every three months to continue sterile compounding.

8.3.2 Proficiency and competency shall be assessed annually to include topics in section 8.1.4.

8.3.3 If compounding in the hazardous clean room, a separate media fill and glove/garb assessment must be successfully completed every three months to continue hazardous sterile compounding.

8.3.4 Preparation process validations must be completed by each sterile compounding technician per sterilization method every six months (PCAB Standard TCRX5-G).

8.3.5 Annual training for sterile compounding technicians will also include written assessments on medication errors, HIPAA policies, blood borne pathogens and hazardous drugs. Each sterile technician will also be visually assessed by a pharmacist on the proper handling of hazardous drugs, if applicable.

8.4 Initial sterile support staff training.

8.4.1 Sterile support staff will complete a structured on-the-job didactic and experiential training program in Bakersfield which provides sufficient hours of instruction and experience in the facility's sterile compounding processes and procedures.

8.4.2 Sterile support staff must successfully complete an initial glove/garbing competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before assisting with clean room activities.

8.4.3 Sterile support staff must successfully complete an initial cleaning assessment before being allowed to clean independently.

8.5 Ongoing sterile support staff training.

8.5.1 Support staff shall complete cleaning and glove/garbing assessments every six months to demonstrate proper cleaning techniques.

9.0 PROCEDURE

9.1 Each pharmacy technician will be responsible for obtaining the appropriate number of continuing education hours, for certification, if applicable.

9.1.1 All licensed professionals are required to display their licensure certificates in the pharmacy area for easy access to regulatory agents and the public.

9.1.2 All licensed professionals shall display any additional information required by the appropriate state board of pharmacy.

9.2 Sterile compounding technicians and support staff involved in the sterile compounding process will be evaluated on their physical ability to perform the assigned compounding responsibility without compromising the integrity of the compound. This will include handicap issues (along with dexterity skills) and any illness or injury.

9.3 All sterile compounding technicians shall undergo training and validation of sterile compounding.

9.3.1 Training should be conducted by expert personnel and through audio-video instructional sources and professional publications in theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare CSPs.

9.3.2 Initial training shall be documented on Initial Sterile Compounding Training, Attachment 1, or equivalent, and Sterile Compounding Technician Training Checklist, Attachment 4, or equivalent, for technicians.

9.3.3 Sterile compounding technicians shall undergo didactic and experiential training as outlined in 8.1.4 and pass written testing initially and annually thereafter for high-risk/Category 3 compounding.

9.3.4 Glove/garbing competency evaluation will be performed prior to initial sterile compounding. Sterile compounding technicians will be reassessed at least every three months thereafter. The initial gloved fingertip/thumb sampling must have zero cfu no less than three times before compounding. Document according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent.

9.3.5 Glove/garbing competency evaluation will be performed three times prior to initial sterile compounding.

9.3.5.1 Sterile compounding technician will be visually observed during the process of performing hand hygiene and garbing procedures by a qualified sterile compounding pharmacist. Document according to SOP

9.130 Sterile Compounding Process Validation (Media Fills), Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel/Cleaning Assessment, Attachment 2, or equivalent.

9.3.5.2 Sterile compounding technician must perform proper hand hygiene and garbing and then, prior to disinfection, a gloved fingertip and thumb sample from both hands of the compounder will be collected onto appropriate agar plates by lightly pressing each fingertip into the agar. Each hand shall be sampled on a separate agar plate. Once the sampling is complete, immediately remove gloves and perform proper hand hygiene procedures before donning a new set of sterile gloves. Document according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel/Cleaning Assessment, Attachment 2, or equivalent.

9.3.5.3 Incubate the plates according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent.

9.3.6 All sterile compounding technicians must successfully complete a high-risk/Category 3 media fill according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent, prior to initially compounding and every three months thereafter.

9.3.6.1 Results are recorded on Initial Sterile Compounding Technician Training. Attachment 1, or equivalent, and Validation of Personnel – Sterile Compounding, Attachment 2, or equivalent, and according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent.

9.3.7 All sterile compounding technicians and support staff must successfully complete SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, Cleaning Assessment for Cleaning and Disinfection Procedures in the Clean Room, Attachment 12, or equivalent, initially and every three months thereafter. Assessment must be completed before personnel initially clean and must include deactivation, decontamination, cleaning and disinfection steps according to SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection, or equivalent, if cleaning in the hazardous clean room.

9.3.8 All sterile compounding technicians must successfully complete preparation process validations every six months, to prove competency, accuracy, and technique on each sterilization method (Attachment 2, or equivalent). This includes a visual inspection of the final preparation by a sterile compounding pharmacist. Potency tests should be performed on each sterilization method initially and every six months thereafter..

9.3.8.1 Validation shall be handled under a "pass/fail" grading system. If the individual performing the procedure does not "pass" then proper retraining and education shall be given and the individual shall not be allowed to perform the procedure again until competency is demonstrated.

9.3.9 Should personnel fail written tests or whose media fill results in microbial colonization or one or more cfu(s) on a glove test between both hands, they shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic deficiencies. Personnel will be restricted from performing sterile compounding or clean room activities until all required evaluations have passed.

9.3.9.1 Positive media fill test results or positive glove/garb competency tests should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls according to applicable SOPs (e.g., 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management, or equivalent) to identify sources of contamination and correct problems in the methods or processes.

9.3.9.1.1 If source of contamination is suspected to have originated/resulted from employee technique, validation test(s) shall be performed which may include garbing assessment, media fill assessment (or an abbreviated version) or cleaning assessment. Document according to SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities and/or SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent.

9.4 Before a sterile compounding technician may compound with hazardous drugs, all initial training requirements outlined in section 9.3 and a separate initial hazardous media fill, according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent, shall be completed. Once complete, a hazardous media fill shall be performed every three months thereafter.

9.4.1 The sterile compounding technician must have sufficient training on the safe handling and disposal of hazardous drugs according to SOPs 7.030 API and Compounded Preparation Spills, 9.090 Proper Disposal of Pharmacy Waste, 13.010 Hazardous Communication Program and 13.020 Deactivation, Decontamination, Cleaning and Disinfection, or equivalent, before beginning hazardous compounding.

9.5 Sterile compounding support personnel will be trained in their specific duties involving the sterile compounding process.

9.5.1 Glove/garbing competency evaluation will be performed prior to entering the buffer room(s). Each support staff member must successfully complete an initial glove/garbing competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before entering the buffer room according to section 9.3.5. Support staff will be recertified at least every six months. Document according to SOP 9.130 Sterile Compounding Process Validation (Media Fills), Hand Hygiene and Garbing Related Practices of Sterile Compounding Personnel/Cleaning Assessment, Attachment 2, or equivalent.

9.5.2 Cleaning assessment shall be performed during initial cleaning (weekly, monthly, quarterly) and must include deactivation, decontamination, cleaning, and disinfection steps if cleaning in the hazardous clean room. Staff will be recertified at least semi-annually. Document assessment according to SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, Cleaning Assessment for Cleaning and Disinfection Procedures in the Clean Room, Attachment 12, or equivalent.

9.6 Should a sterile compounding support staff member fail a glove test with one or more cfu(s) between both hands, they shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic deficiencies. They will be restricted from buffer room access until all required evaluations have passed.

9.6.1 Positive glove/garb competency tests should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls according to applicable SOPs (e.g., 1.030 Deviations – OOS

and Corrective and Preventative Action (CAPA) Management, or equivalent) to identify sources of contamination and correct problems in the methods or processes.

9.6.1.1 If source of contamination is suspected to have originated/resulted from employee technique, validation test(s) shall be performed which may include a garbing assessment or cleaning assessment. Document according to SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities and/or SOP 9.130 Sterile Compounding Process Validation (Media Fills), or equivalent.

9.7 Training assessments shall be documented and retained appropriately in the designated employee training binder for at least three years beyond the employee's employment.

9.8 The Sterile Compounding Pharmacist Supervisor shall be responsible for determining if the employee or procedure requires evaluation more frequently than every three months.

9.9 Annual training for all sterile compounding technicians will also include didactic training in blood borne pathogens and written assessments on medication errors and HIPAA procedures. Annual hazardous drug training must be completed according to SOP 13.010 Hazardous Communication Program, or equivalent. All training assessments will be recorded on Annual Sterile Compounding Technician Training, Attachment 3, or equivalent, for each calendar year and retained appropriately in the designated employee training binder.

10.0 ATTACHMENTS

10.1 Attachment 1 – Initial Sterile Compounding Technician Training

10.2 Attachment 2 – Sterile Compounding Process Validation

10.3 Attachment 3 – Annual Sterile Compounding Technician Training

10.4 Attachment 4 – Sterile Compounding Technician Initial Training Checklist

11.0 HISTORY

Version Number	Review Date	Effective Date	Description of Change
1.0	10-2009-12/2009	12-14-2009	New SOP
2.0	11-2-2010	1-1-2011	Annual Review; procedural changes
2.0	12-13-11	1-1-2011	Annual Review; No Changes
3.0	4-11-2013	6-14-2013	Annual Review; procedural changes (see draft for specifics)
4.0	8-13-2013	8-14-2013	See draft for specific changes
5.0	1-17-2014	1-20-2014	See draft for specific changes
6.0	2-18-2014	2-19-2014	See draft for specific changes
Version Number	**Review Date**	**Effective Date**	**Description of Change**
7.0	3-6-2014	6-12-2014	See draft for specific changes
8.0	9-4-2014	9-9-2014	Revised Attachment 3 – page 2
9.0	4-22-2015	5-4-2015	Annual Review; Extensive changes; See hard copy for details

10.0	6-4-2015	6-5-2015	Moved Attachments 2 and 3 to SOP 9.30; Renumbered Attachments 4 and 5
11.0	7-13-2015	7-17-2015	Updated Attachment 2
12.0	1-27-2016	2-24-2016	Annual Review; Updated Attachment 3; Updated SOP to include pharmacists; see hardcopy for details
13.0	6-1-2016	6-16-2016	Updated for new clean room – see hardcopy for specific changes
14.0	2-10-2017	2-17-2017	Annual Review; Updated 6.2, 9.3.2, 9.4.4, 9.4.5.3, 9.4.8, and 9.4.10; Minimal grammar formatting
15.0	9-28-2017	10-2-2017	Extensive updates to training procedures (CA and TX regulations and CA BOP inspector recommendations) see hard copy for details
16.0	1-16-2018	2-5-2018	Annual Review; Updated 6.1; Added 8.3.3, 8.4-8.5.2; Updated SOP to include reference to support staff as applicable; Updated references to current versions; Updated SOP references on Attachment 4; Grammar throughout
17.0	2-18-2019	4-2-2019	Annual Review; Updated 9.3.9, references to current versions and Attachments 1 and 4; Minor grammar/formatting throughout
18.0	11-19-2019	12-9-2019	Updated for USP <800>; Added 4.5, 8.2.2.1; Updated 9.3.7, 9.4, 9.4.1, 9.5.2, 9.9 and Attachments to include HD training
19.0	6-12-2020	8-17-2020	Annual Review; Added 5-.1 – 5.3; Updated 9.3.7, 9.7, Attachment 2; Grammar/formatting throughout
20.0	6-14-2021	12-13-2021	Annual Review; Updated 8.3, 8.5, Attachments 1, 3, and 4; Grammar/formatting throughout.
21.0	11-10-2022	12-27-2022	Annual Review; Updated Precision Pharmacy to Precision Equine (Precision) throughout; Removed monthly glove test requirement throughout; Grammar/formatting
22.0	1-17-2023 10-13-2023	1-31-2024	Annual Review; Updated 9.3.8, Attachment 2, 3,4 to add potency testing frequency for PCAB; Additional updates for USP, see hardcopy and electronic file for specifics.
23.0	9-24-2024	10-25-2024	Annual Review; Updated Precision Equine to Wedgewood Pharmacy throughout; Updated title for Sterile Compounding Pharmacist Supervisor throughout; Updated 8.3.4 and 9.3.8; Added 4.9 and 9.3.8.1; Added "or equivalent" to Bakersfield SOPs to allow for Sop integration; Updated LFW language to batch ticket"

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Initial Sterile Compounding Technician Training

New sterile compounding technicians must complete all

Check One:
□ Non-Hazardous Clean Room
□ Hazardous Clean Room

Review and demonstrate the following: **Read USP <797> and written test:** _____

1. Aseptic hand washing/ proper garbing assessment Assessment Completed on: _____

2. Glove Test/Assessment Completed and Passed:

Initial Glove/Garb Test □ Date: _____ Second Glove/Garb Test □ Date: _____ Third Glove/Garb Test □ Date: _____

3. Correct cleaning of LAFW or BSC (circle one) Assessment Completed on: _____

4. Cleaning assessment completed Assessment Completed on: _____

5. Demonstrate aseptic technique via media fill (also demonstrating knowledge of first air and the importance of where materials are placed)

Initial media fill completed on: _____

6. Initial sterile training checklist completed on: _____

7. Formal training completed on: _____

Title of training program: _____

_____

Hours of program: _____

8. Demonstrate knowledge of each method of sterilization by completing a process validation using a dry heat sterilized, a filtered, and an autoclaved preparation. (Not required for both non-hazardous and hazardous; does not need to be repeated for each)

Initial Dry Heat Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency □

Initial Filtration Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency ☐

Initial Autoclaved Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency ☐

9. Process Validation Six Months after Initial validations above:

Dry Heat Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency ☐

Filtration Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency ☐

Autoclaved Assessment Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#:_____ Potency ☐

Reviewed:_____ Date:_____

Sterile Compounding Pharmacist Supervisor

STERILE COMPOUNDING PROCESS VALIDATION

Personnel involved in compounding preparations shall be validated for proper technique and understanding of the concepts behind the procedures to be performed. Validation shall be handled under a "pass/fail" grading system. If the individual performing the procedure does not "pass" then proper retraining and education shall be given and the individual shall not be allowed to perform the procedure again until competency is demonstrated.

Date: _____ **Personnel validated:** _____

Name of preparation: _____ **Lot #** _____

Method used to validate personnel (Circle One):

Media Fill: Initial Non-Haz Initial HD Ongoing Non-Haz. Ongoing HD

Preparation Process Validation

Complete the shaded box if method is for process validation of preparation. Not required to fill out for media fills.

Preparation Form: ☐ Solution ☐ Suspension ☐ Ointment ☐ Other _____

Sterilization Method: ☐ Filter Sterilization ☐ Steam Sterilization ☐ Dry Heat Sterilization

Sterility Test: ☐ Pass ☐ Fail

Potency Tested? ☐ NO ☐ YES If yes, Results: _____

Note: A potency test should be performed on each sterilization method every six months.

Outcome of validation: ☐ Pass ☐ Fail, re-validation date: _____

Comment: _____

_____

_____

_____

_____

Signature: _____ **Date:** _____
Personnel

Signature: _____ **Date:** _____
Sterile Compounding Pharmacist Supervisor

Annual Sterile Compounding Technician Training

Must complete all tasks within each calendar year

Name: _____ Year: _____

Initial Training Completed on: ____/____/_____ **Initial Glove/Garb Assessments Completed on:** ____/____/_____

Review and demonstrate the following:

1. Cleaning Assessment Completed

1st Cleaning Assessment Completed on: __/___/_____ 2nd Cleaning Assessment Completed on: __/___/_____

3rd Cleaning Assessment Completed on: __/___/_____ 4th Cleaning Assessment Completed on: __/___/_____

2. Demonstrate aseptic technique via media fill (also demonstrating knowledge of first air and the importance of where materials are placed)

1st Media Fill Completed on: ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

2nd Media Fill Completed on: ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

3rd Media Fill Completed on: ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

4th Media Fill Completed on: ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

1st Hazardous Media Fill Completed on (if applicable) : ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

2nd Hazardous Media Fill Completed on (if applicable): ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

3rd Hazardous Media Fill Completed on (if applicable) : ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

4th Hazardous Media Fill Completed on (if applicable): ___/___/_____ ☐ Pass ☐ Fail ☐ OOS

Glove/Garbing Assessment: ___/___/_____ ☐ Pass ☐ Fail Aseptic Technique/Cleaning Assessment: ___/___/_____ ☐ Pass ☐ Fail

Annual Sterile Compounding Technician Training

Must complete all tasks within each calendar year

3. Complete process validations using each method of sterilization: Filter sterilization, Dry Heat sterilization, Steam sterilization

A potency test should be performed on each sterilization method every six months.

1st *Dry Heat Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

1st *Filtration Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

1st *Autoclaved Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

2nd *Dry Heat Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

2nd *Filtration Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

2nd *Autoclaved Assessment* Completed on: ___/___/_____ RPH: _____

Drug Name & Lot#: _____ Potency ☐

4. Annual Review:

Hazardous Training: Written Assessment: ___/___/_____ Hands-on Assessment: ___/___/_____

Didactic Training: ___/___/_____ Medication Error Prevention Training: ___/___/_____ HIPAA Training: ___/___/_____

Annual Quiz ___/___/_____ Blood Borne Pathogens Training: ___/___/_____

Cultural Competency 1.0 hour CE (CA BOP): _____

Annual Sterile Compounding Technician Training

Must complete all tasks within each calendar year

5. Additional Sterile Staff Trainings:

Reviewed:_____ **Date:**_____

Sterile Compounding Pharmacist Supervisor

Wedgewood Pharmacy, Bakersfield

Sterile Compounding Technician Training Checklist

EMPLOYEE INFORMATION

Name: _____ Start date: _____

Position: _____ Manager: _____

FIRST DAY

☐ Assign "buddy" employee(s) to answer general questions and demonstrate tasks/procedures. Name(s): _____

POLICIES

☐ Read, sign, and date applicable policies (not limited to SOP's listed).

**List only includes sterile policies. If not already trained in non-sterile compounding, may need to read applicable non-sterile compounding policies.

☐ Read and complete test on USP <797>.

Bakersfield SOPs listed in this document may be replaced with equivalent Wedgewood corporate or cross site SOPs or are in addition to Wedgewood corporate or cross site SOPs.

- 1.060 General Aseptic Technique
- 2.030 Sterile Compounding Technician and Support Staff Qualification
- 3.010 Sterile Compounding Area Requirements
- 3.020 Cleaning and Maintenance of the Clean Room Facilities
- 3.030 Environmental Monitoring of the Clean Room Facilities
- 4.060 Use, Verification and Maintenance of the Incubators
- 4.110 Use and Maintenance of the Traceable Digital Humidity/Temperature Meters
- 4.430 Use, Verification and Maintenance of the Data Loggers
- 8.010 Sterilization and Depyrogenation
- 9.080 Preparation Quarantine, Storage and Release
- 9.110 Proper Hand Washing Procedure
- 9.120 Required Garb for Clean Room Facilities Access
- 9.140 Sterile Compounding Finished Preparation Testing
- 9.220 Contract Testing Laboratory Selection and Desk Audit

TOURS OF CLEAN ROOM FACILITY

☐ Tour of facility, including:

- Non-Hazardous Clean Room Preparation Room
- Non-Hazardous Garb Room
- Non-Hazardous Buffer Room
- Hazardous Airlock
- Hazardous Prep Room
- Hazardous Garb Room
- Hazardous Buffer Room
- Dressing Room
- Testing Room (Autoclaves, Branson, Dry Heat Oven)
- Device Storage
- Incubators
- Spill Kits/Eye Wash/Fire Extinguishers
- Finished Preparation Storage
- Expired storage
- Controlled Substance cabinet
- Chemical Storage

STERILE COMPOUNDING TRAINING CHECKLIST

Before the trainer can sign each section, he/she must demonstrate topics listed within the section to the trainee, then the trainee must demonstrate the procedures to the trainer. Once the trainer feels like the trainee has sufficiently demonstrated competence in the specific topic, the trainer may sign off on the section.

☐ Review job description and performance expectations and standards.

☐ Initial Formal Training completed on:_____ Program Title:_____

Continuing Education Hours: _____

☐ Initial Glove Tests (x3) completed on:_____

☐ Initial Media Fill completed on: _____ **Circle One:** Non-Hazardous OR Hazardous

This checklist may not be all-inclusive of all SOPs. Training and procedures at Wedgewood Pharmacy, Bakersfield and is subject to change without officially updating all SOPs.

*In order to compound in each cleanroom (non-hazardous or hazardous), the technician must complete a formal training covering techniques in aseptic processing specific to the techniques needed for that room, pass three glove tests with no growth, and pass a high-risk/Category 3 media fill in the room they will be compounding in before compounding sterile preparations for dispensing.

OVERVIEW OF ISO CLASSIFICATIONS OF ROOMS

Date Completed: _____
Employee Initials: _____
Trainer Initials: _____

- ☐ ISO Class 5 Areas
  - -LAFW (Non-Hazardous Cleanroom)
  - -BSC Class 2 (Hazardous Cleanroom)
- ☐ ISO Class 7 Areas
  - -Non-hazardous/hazardous buffer rooms
  - -Hazardous garb room
- ☐ ISO Class 8 Areas
  - -Non-hazardous garb room
  - -Non-hazardous/hazardous prep room
  - -Hazardous air lock

☐ Read, sign, and date SOP 3.030 Environmental Monitoring of the Clean Room Facilities, or equivalent.

☐ Review air flow concepts of positive and negative pressure, to include principles of high-efficiency particulate (HEPA)-filtered unidirectional airflow within the ISO Class 5 area.

☐ Read, sign, and date SOP 4.260 Use and Maintenance of the Dwyer Mark II Manometer, or equivalent.

HANDWASHING PROCEDURES/GARBING- HAZARDOUS AND NON-HAZARDOUS

Date Completed: _____
Employee Initials: _____
Trainer Initials: _____

☐ Review Precision Pharmacy's Hazardous Drug List.

-Read, sign, and date SOP 13.010 Hazardous Communication Program, or equivalent.

-Read, sign, and date SOP 13.020 Deactivation, Decontamination, Cleaning, and Disinfection, or equivalent.

☐ Personal protective equipment

- Including location of supplies and when to wear appropriate equipment.

☐ Gowns:

-Disposable hazardous

-Reusable non-hazardous

-Acid apron

☐ Coveralls:

-Disposable hazardous

☐ Gloves

-Latex (powder-free)

-Nitrile (Sterile and Non-Sterile)

-ASTM-tested chemo gloves (2 pairs required for hazardous compounding) (Sterile and Non-Sterile)

-Acid gloves

☐ Masks

-N95 for powders

-N95 respirator fit test performed on: _____

-Respirator with charcoal cartridges

-Respirator fit test performed on: _____

-Surgical mask- not to be used when weighing out powders.

☐ Goggles

☐ Face Shields

☐ Hair Nets

☐ Non-Skid Shoe Covers

-Two pairs required for hazardous compounding.

☐ Garbing procedures required for buffer room access

☐ Read, sign, and date SOP 9.110 Proper Hand Washing Procedure, or equivalent.

☐ Read, sign, and date SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent.

-Initial sterile compounding garb assessments completed on: _____/_____/_____

This checklist may not be all-inclusive of all SOPs. Training and procedures at Wedgewood Pharmacy, Bakersfield and is subject to change without officially updating all SOPs.

BASIC STERILE COMPOUNDING TECHNIQUES

Date Completed: _____
Employee Initials: _____
Trainer Initials: _____

☐ Documentation of the Compounding Process

-Go over LFW Checklist, SOP 9.040 Attachment 1, or equivalent: yield, end preparation testing forms, filter info, etc.

-Pull all chemicals and check expiration dates. Check that none of the chemical expiration dates are shorter than the expected BUD of the batch. If there is a shorter date, check with schedule to see if that is okay.

- Log into EBR and scan batch ticket barcode.

-READ ALL DIRECTIONS BEFORE STARTING.

-Choose correct PPE based on the compound and cleanroom (hazardous/non-hazardous).

- Clean the hood and scale with the appropriate cleaners and record in batch notes.

☐ **Powder Checks**

-Check units on scale display are GRAMS.

-Make sure scale is clean from previous use. If not, perform cleaning procedure.

-Check bubble is in middle of circle to ensure scale is level. If not, maneuver the legs to become level.

-Scan all equipment needed to compound into the EBR system (including scales, hood, pH meters, hot plates, etc.)

-Tare weighing container. Make sure scale says zero (0). Hit print button on scale to capture the tare.

-Weigh powder to the correct weight. Hit the print button on the scale again for EBR to capture the weight.

- Continue this process with all ingredients (powders and liquids).

-Clean scale.

-NEVER MOVE A SCALE FROM ITS CURRENT HOOD.

-Change or clean gloves between weighing out each powder to prevent cross contamination.

-Proper measuring and mixing

☐ **Liquid Checks**

-Determine volume needed for log and choose the appropriate equipment (beaker, syringes).

-How to read volume in an oral syringe.

-How to read the volume in a beaker (bottom of meniscus) or graduated cylinder.

-Label beaker with contents.

-Determine which liquid is QS agent.

-This is the liquid that will be used to bring the compound to its final volume.

-Does not need to be poured out of original container until the compound needs to be brought to final volume.

-Proper measuring and mixing

☐ **Processing Agents/pH Adjusters**

-These are formulas made in the pharmacy that will be used in another formula.

-pH adjusters are processing agents and they are only required to adjust pH.

-Ex: Sodium Hydroxide, Hydrochloric Acid, Sulfuric Acid, Citric Acid

-If the pH is too high and you need it to decrease use an acid according to the log directions.

-If the pH is too low and you need it to increase, use a base according to the log directions.

-Go over proper storage containers for specific pH adjusters.

☐ **Q.S. Checks**

-Once everything is mixed according to directions and QS'ed to the appropriate volume, take a picture of the beaker with the final volume and call for a sterile compounding pharmacist to do the QS check.

-Have the pharmacist document in Batch Notes that they did the QS check.

- If consistency is ready, have RPH check consistency at this point as well.

-Once final volume has been checked, compound can be filtered or packaged into final dispensing container to be autoclaved.

☐ **Labels**

-Explain who to give log to so labels can be made.

Have a RPH check the labels

☐ **Final Batch Verification/QC Checks**

Before the pharmacist can close a batch, the technician must perform all of the following in EBR:

Enter the amount of compounded product into production and hit Finish

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Make sure all BOM items used in the compounding process is scanned into EBR
Make sure all equipment used are scanned into EBR
Scrap any materials or products that were discarded during the compounding process.
Make sure all Technician QC checks are completed (PriComp, SecComp, PriPack, SecPack, BWFailQty, BWTestTech)
Take a picture of the LFW Checklist page
Take a picture of the page with all the lot#s and exp dates of BOM items

☐ **General Aseptic Technique**

-Use processes and procedures from formal training.

-Principles of movement of materials and personnel within the compounding area. Decrease talking and fast movements while in the buffer room.

-DO NOT touch face mask or face with sterile gloves on.

-If there is a concern about touch contamination with a filter or other critical site, dispose of the device.

-If leaving the ISO Class 5 Environment for any reason, spray gloves with sterile IPA before re-entering hood.

-All equipment, devices and supplies must be wiped down with sterile IPA before entering the ISO Class 5 environment.

EQUIPMENT

-Go over location in the pharmacy and how to use specific equipment

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ Primary Engineering Controls (ISO 8 Environment)-

-Powder Containment Hood

- Used only for non-hazardous compounding when weighing and mixing powders.

-Biological Safety Cabinet (BSC)- Class I

-Ventilated exhaust to the outside.

- Used for hazardous (or non-hazardous) compounding when weighing and mixing powders.

-Velocity meter

-Large hoods must have main flap down while standing in front of hood. If you need to walk away, make sure the second flap is down.

☐ Primary Engineering Controls (ISO 5 Environment)-

-Laminar Airflow Workbench (Non-Hazardous)

- Air flows from the HEPA filter horizontally across the work surface toward the compounder.

- Used only for non-hazardous sterile compounding.

-Biological Safety Cabinet (BSC)- Class II

-Ventilated exhaust to the outside.

-Air flows from the HEPA filter at the top of the hood vertically down toward the work surface. Air exits through the grates before coming in contact with the compounder.

-Must be used when compounding hazardous drugs.

-Velocity meter

-Large hoods must have main flap down while standing in front of hood. If you need to walk away, make sure the second flap is down.

☐ Read, sign, and date SOP 4.200 Use and Maintenance of the Streamline and Air Sciences Containment/Fume/BSC Class I & Class II/LAFW, or equivalent.

☐ Beakers

-Must use calibrated beakers when bringing formula to volume or measuring out liquids.

-All beakers and glassware should be depyrogenated before using to make sterile compounds.

☐ Read, sign, and date SOP 4.300 Use, Calibration and Maintenance of Beakers, or equivalent.

☐ Spatulas: plastic, metal

☐ Mortar and Pestle

-Glass: suspensions

☐ Hot Plates

☐ Read, sign, and date SOP 4.080 Use, Calibration and Maintenance of the Stirring Hot Plates, or equivalent.

☐ Spin Bars: small, medium, large, cross (used for small quantity).

☐ Scales

☐ Read, sign, and date SOP 4.070 Use, Verification, Certification, Calibration and Maintenance of the Balances and Scales, or equivalent.

-Refer to SOP of maximum and minimum weights allowed for each scale.

-Weighing Equipment: weigh boats, beakers, resealable bags, utensils.

☐ Homogenizers

☐ Read, sign, and date SOP 4.140 Use and Maintenance of the IKA (Homogenizer) Dispersion Tool, or equivalent.

-How to assemble and disassemble.

-Start on lowest setting when turning on and increase as needed.

-Cleaning procedures.

☐ pH Meters

☐ Read, sign, and date SOP 4.360 Use, Calibration and Maintenance of the pH Meters, or equivalent.

-Milwaukee meter should be used for high pH (over 10).

-Paper strips are not as accurate.

☐ Thermometers

☐ Dry Heat Oven

☐ Read, sign, and date SOP 4.380 Use, Verification and Maintenance of the Thermo Scientific Heratherm Dry-Heat Oven, or equivalent.

-Used to sterilize non-aqueous preparations that are resistant to heat degradation.

-Used to depyrogenate glassware and other utensils.

☐ Autoclaves

☐ Read, sign, and date SOP 4.030 Use, Verification and Maintenance of the Tuttnauer EZ10 Electronic Tabletop Autoclave, or equivalent.

-Used to sterilize reusable garb, vials, aqueous preparations and other equipment that cannot be sterilized using dry heat.

-Go over settings to sterilize equipment and preparations.

-Autoclave bags and steam indicator.

☐ Biological Indicators

☐ Read, sign and date SOP 8.020 Biological Indicators, or equivalent.

-Microorganisms encapsulated in glass or plastic and placed inside the autoclave to indicate steam sterilization is effective in killing microbes.

-Glass biological indicators must be placed inside one filled preparation bottle per autoclave. Also need to place a plastic biological indicator on tray per autoclave.

-Chemical indictors placed in dry heat cycle to prove heat cycle reached a certain temperature.

☐ Branson Sonicator

☐ Read, sign, and date 4.230 Use and Maintenance of the Branson Ultrasonic Cleaners, or equivalent.

-Used to break up clumps in autoclaved suspensions.

-Go over settings and when to use.

☐ Repeater Pump

☐ Read, sign, and date 4.220 Use and Maintenance of the Baxa Repeater Pump, or equivalent.

-Go over how to calibrate fill volumes for oil and water-based compounds.

END PREPARATION TESTING

☐ Quarantine Forms

-How to fill them out and what tests need to be performed.

☐ Sterility Testing

-Processes to achieve and maintain sterility and apyrogenicity, if applicable

-Must be performed on all sterile preparations.

-Send the appropriate amount of containers based on the batch size chart.

-Go over procedure on how to send sample to shipping.

-Sterility testing can take 14-18 days depending on the preparation.

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ Pyrogen Testing

-Performed on all injectable sterile preparations. This includes preparations that will remain within a body cavity (e.g. Belly Jelly).

-Determines the amount of endotoxin units in a preparation and it must be lower than the predetermined limit to pass.

-Endotoxins are remnants of bacterial cells that are too small to be filtered out of a preparation but when in high amounts can cause a pyrogenic reaction in the animal it is injected into.

-Endotoxin testing is done by a third party lab.

☐ Bubble Point Testing

-Required for all preparations that are filtered.

-Tests the integrity of the filter by ensuring it can withstand a specific pressure applied to the membrane.

☐ Read, sign, and date SOP 9.210 Integrity Test Method by Bubble Point, or equivalent.

☐ Particulate Observation

-Required for all sterile solutions and some suspensions.

-Bottles with particulate will be discarded.

CLEANING/MAINTENANCE OF THE CLEANROOM AND DISPOSAL OF WASTE

☐ Cleaning Agents

-Disinfectant: Decreases microbial load by killing microorganisms.

-Detergent: Cleans residues and dirt.

-Sporicidal: Robust cleaning agent that kills spores that some microorganisms leave behind after the cell dies.

-Deactivation and Decontamination: Required when compounding with hazardous drugs. Transforms and removes the hazardous drug contaminants on surfaces.

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ Read, sign, and date SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent.

☐ Read, sign, and date SOP 7.030 API and Compounded Preparation Spills, or equivalent.

☐ Review hood cleaning procedures.

☐ Review contact times of specific cleaning agents currently in use and the order they are used in.

☐ Fill out cleaning and maintenance log when complete with date, time, and initials.

☐ When compounding in the preparation room: keep all bags, weigh boats and other disposable supplies within the powder hood. When cleaning, put all waste in a resealable plastic bag. Seal and wipe outside of bag before bringing out of hood.

-For hazardous compounds, dispose of bag in hazardous waste container.

-For non-hazardous compounds, dispose bag in trash.

☐ Review locations of spill kits, eye wash stations, fire extinguishers.

☐ Daily temperature and humidity log requirements.

☐ Daily pressure readings.

☐ Read, sign and date SOP 4.430 Use, Verification, and Maintenance of the Data Loggers, or equivalent.

Cleaning assessment completed on:_____

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MEDIA FILLS AND PREPARATION PROCESS VALIDATIONS

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ Media Fills

-TSB solution is substituted for compounded preparation to test aseptic technique.

-Must be completed quarterly for high-risk compounding.

-If compounding hazardous sterile compounds a separate media fill will also need to be performed quarterly.

-A didactic test will be given at the same time of the media fill.

☐ Read, sign, and date SOP 9.130 Sterile Compounding Process Validations (Media Fills), or equivalent.

Initial media fill completed on: _____ Lot #: _____

Circle One: Hazardous Non-Hazardous

☐ Preparation Process Validations

-Must be completed for every type of sterilization method initially and then every six months thereafter. Complete below for first validation, document second validation in six months according to SOP 2.030 Sterile Compounding Technician and Support Staff Qualification, Attachment 2, or equivalent.

Filter Sterilization Process Validation:

Formula Name: _____
Lot #: _____
Potency Result: _____

Steam Sterilization Process Validation:

Formula Name: _____
Lot #: _____
Potency Result: _____

Dry Heat Sterilization Process Validation:

Formula Name: _____
Lot #: _____
Potency Result: _____

☐ Cleaning Assessments

-Must be performed quarterly on a weekly or monthly clean to ensure cleaning technique is sufficient.

ENVIRONMENTAL/PERSONNEL MONITORING

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ Monthly sampling intervals for:

-Clean rooms

☐ Know what action and alert levels are.

☐ Read, sign, and date SOP 4.340 Use and Maintenance of the SAS Super 180 Microbiological Air Sampler, or equivalent.

☐ Read, sign, and date SOP 3.030 Environmental Monitoring of the Clean Room Facilities, or equivalent.

QUALITY ASSURANCE

Date Completed:_____
Employee Initials:_____
Trainer Initials:_____

☐ When to fill out an OOS form

- Any batch that was failed for any reason.

-Failure of an end preparation test.

-Temperature/Humidity/Pressure out of range.

☐ Read, sign, and date SOP 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management, or equivalent.

Employee Signature: _____ Date: _____
Trainer Signature: _____ Date: _____
Reviewed By: _____ Date: _____

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PRECISION EQUINE	
TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITIES	
SOP NUMBER: 3.020	**VERSION NUMBER: 26.0**
Authorized By:	Date:
Written By: PCCA/Taggs/Wussow/Shine/Doherty	Date: 11-8-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for cleaning and maintenance of the clean room facilities.

2.0 SCOPE

2.1 This procedure applies to the Precision Equine (Precision) clean room facilities under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopoeia <797> and <800>.

2.2 This policy must be followed to reduce the amount of particulate matter and microbial contamination.

3.0 RESPONSIBILITY

3.1 The designated sterile compounding supervisor shall supervise this procedure to ensure compliance and documents have been completed for all personnel responsible for cleaning and maintenance of the clean room facilities.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <800> "Hazardous Drugs – Handling in Healthcare Setting"

4.3 SOP 1.060 General Aseptic Technique

4.4 SOP 3.030 Environmental Monitoring of the Clean Room Facilities

4.5 SOP 9.120 Required Garb for Clean Room Facilities Access

4.6 SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection

4.7 2023 Lawbook for Pharmacy; California and proposed sterile compounding regulations April 2023

4.8 Drug Distribution and Control: Preparation and Handling Guidelines; ASHP Guidelines on Handling Hazardous Drugs

4.9 New Jersey Rule 13-39:5.11. Control and monitoring of temperature of prescription drugs and chemicals.

4.10 Critical Point; Hazardous Drug Compounding Tips and Best Practices; Kate Douglas, MS, RN, CRNI and Eric Kastango, RPh, MBA, FASHP

5.0 DEFINITIONS

5.1 LAFW – laminar airflow workbench

5.2 BSC – biological safety cabinet

5.3 Cleaning – the process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. (USP <797>)

5.4 Cleaning agent – An agent, usually containing a surfactant, used for the removal of substances (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces. (USP <797>)

5.5 Daily means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperatures are required, then daily means every 24 hours. (2023 CA 1735.1)

5.6 Disinfectant – A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. (USP <797>)

5.7 Sanitizing agent - An agent for reducing, on inanimate surfaces, the number of microorganisms (e.g., 70% isopropyl alcohol). (USP <795>)

5.8 Sporicidal – a chemical or physical agent that destroys bacterial and fungal spores when used at a sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms (USP <797>).

5.9 PPE – personal protective equipment

5.10 Primary Engineering Control (PEC) - a device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.11 IPA – isopropyl alcohol

5.12 CSP – compounded sterile preparation

5.13 EPA – United States Environmental Protection Agency

6.0 FREQUENCY

6.1 Non-hazardous clean room cleaning procedure.

6.1.1 Daily, when compounding occurs.

6.1.1.1 Clean and disinfect all in use work surfaces (e.g., counters, carts) and floors.

6.1.1.2 Clean and disinfect all ISO 5 surfaces of LAFW(s) with sterile cleaning and disinfecting agents.

6.1.1.2.1 Additionally, sterile 70% IPA must be applied to the ISO 5 work surfaces immediately before initiating compounding.

6.1.1.2.2 Sterile 70% IPA must be applied to the ISO 5 horizontal work surface every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the LAFW must be disinfected immediately after compounding.

6.1.1.3 Clean and disinfect all contact surfaces of the sink.

6.1.1.4 Clean and disinfect mop pole(s).

6.1.1.5 Clean and disinfect all in-use equipment. Equipment inside the LAFW(s) shall be cleaned and disinfected with sterile agents.

6.1.1.6 Clean and disinfect pass-throughs.

6.1.1.7 Remove and discard trash.

6.1.1.8 Record the temperature and humidity.

6.1.1.9 Record pressure differential.

6.1.2 Weekly

6.1.2.1 Includes all requirements listed in section 6.1 utilizing a sporicidal agent on the following:

6.1.2.2.1 Disinfect inside the LAFW(s), including equipment, with a sterile sporicidal agent.

6.1.2.2.2 Disinfect pass-throughs.

6.1.2.2.3 Disinfect work surfaces

6.1.2.2.4 Disinfect floors.

6.1.3 Monthly

6.1.3.1 Perform and document daily requirements listed in section 6.1.2.

6.1.3.2 Clean and disinfect with a sporicidal agent the waste receptacle.

6.1.3.3 Clean and disinfect with a sporicidal agent all exposed supplies stored in the clean room facilities.

6.1.3.4 Clean and disinfect with a sporicidal agent inside and outside of all items used for storage (e.g. shelving, carts, plastic bins, cabinets, etc.).

6.1.3.5 Clean and disinfect with a sporicidal agent to all walls and ceilings.

6.1.2.6 Clean and disinfect with a sporicidal agent inside of storage totes.

6.1.2.7 Clean and disinfect with a sporicidal agent the surfaces of the sink.

6.1.4 Cleaning steps may be followed with sterile water to remove residue, if recommended by the manufacturer.

6.1.5 In the LAFW(s) sterile 70% IPA must be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove residue.

6.1.6 The final cleaning step should be done with sterile IPA.

6.2 Hazardous clean room cleaning procedure – all steps listed in sections 6.2.1 through 6.2.6 below shall be carried out according to SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection.

6.2.1 Daily, when compounding occurs.

6.2.1.1 Deactivate, decontaminate, clean, and disinfect all in use work surfaces (e.g., counters, carts).

6.2.1.2 Clean and sanitize floors.

6.2.1.3 Deactivate, decontaminate, clean, and disinfect all ISO 5 surfaces of BSC.

6.2.1.3.1 Additionally, sterile 70% IPA must be applied to the ISO 5 work surfaces immediately before initiating compounding.

6.2.1.3.2 Sterile 70% IPA must be applied to the ISO 5 horizontal work surface every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the BSC must be disinfected immediately after compounding.

6.2.1.4 Deactivate, decontaminate, clean, and disinfect all contact surfaces of the sink.

6.2.1.5 Deactivate, decontaminate, clean, and disinfect mop pole(s).

6.2.1.6 Deactivate, decontaminate, clean, and disinfect all in-use equipment.

6.2.1.7 Remove and discard trash.

6.2.1.8 Deactivate, decontaminate, clean, and disinfect trash receptacle.

6.2.1.9 Record the temperature and humidity.

6.2.1.10 Record pressure differential.

NOTE: If no hazardous compounding is occuring on that day, deactivation and decontamination step may be omitted and documented.

6.2.2 Weekly

6.2.2.1 Deactivate and decontaminate floors. Followed by a clean with a sporicidal agent utilizing the appropriate dwell time specified by the manufacturer.

Deactivate, decontaminate, clean and disinfect pass-throughs.

6.2.2.2 Each scheduled weekly clean will replace a daily clean.

6.2.3 Monthly

6.2.3.1 Perform and document requirements listed in section 6.2.1 and 6.2.2.

6.2.3.2 Clean and disinfect all exposed supplies stored in the clean room facilities with a sporicidal agent.

6.2.3.3 Clean and disinfect the inside and outside of all items used for storage (e.g., shelving, carts, plastic bins, cabinets, etc.) with a sporicidal agent.

6.2.3.4 The front valance of the BSC must be removed and deactivated, decontaminated, and cleaned with sporicidal agent and disinfected along with the work tray. Personnel performing this task must wear a full-face piece respirator.

6.2.3.5 Clean, disinfect and apply a sporicidal agent to the surfaces of the sink.

6.2.3.6 Clean and disinfect all walls and ceilings with a sporicidal agent.

6.2.3.7 Each scheduled monthly clean will replace a weekly clean.

6.2.4 All steps shall be performed utilizing the manufacturer's recommendations (e.g., wipe methods, dwell times, etc.).

6.2.5 If environmental monitoring trends show unfavorable results, step 6.2.3.1 may need to be carried out with different agents used in the previous clean.

6.3 Cleaning may be performed on a more frequent basis than outlined in this SOP (e.g., weekly as opposed to monthly).

7.0 EQUIPMENT & SUPPLIES

7.1 Mop(s) with disposable cleaning pads labeled for use on the appropriate surfaces of each clean room facility only.

7.2 Lint-free or low shed towels or wipes.

7.3 70% sterile isopropyl alcohol (IPA)

7.4 Appropriate sanitation agents:

7.4.1 Daily sanitizing agents: quaternary ammonium solution (e.g. TexQ, Decon Quat, or TB1-3300), chlorine-based solution (e.g. BruTab or Bru Clean TbC (Floors)

7.4.2 Sporicidal agents: hydrogen peroxide with peracetic acid (Decon-Spore and Peridox RTU), bleach (Decon sodium hypochlorite)

7.4.3 Deactivation/decontamination agents: EPA-registered oxidizer (e.g., Peridox RTU)

7.4.4 Germicidal detergents: DeconClean

7.4.5 Disinfectant: sterile 70% IPA

7.5 Sterile water

7.6 Waste container liners.

7.7 Step stool, if needed.

7.8 Room thermometer and hygrometer.

7.9 Hood pressure monitors

7.10 Room pressure monitors (manometers)

7.11 PPE – personnel protective equipment

7.12 Dedicated mop poles for each room.

8.0 GENERAL INFORMATION

8.1 Surfaces in cleanrooms used to prepare compounded sterile preparations must be cleaned, disinfected and sporicidal disinfectants applied according to the frequencies described in this SOP.

8.2 Additionally, in a PEC, sterile 70% IPA must be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. Sterile 70% IPA must also be applied immediately before initiating compounding. During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 min if the compounding process takes 30 min or less. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.

8.3 Surfaces must be cleaned prior to being disinfected with an EPA-registered disinfectant unless an EPA-registered one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. A sporicidal disinfectant must also be applied. Some EPA-registered one-step disinfectant cleaners may have sporicidal properties.

8.4 Sanitizing solutions/disinfectants

8.4.1 Quaternary ammonium disinfectant (e.g., TexQ, Decon Quat or TB1-3300)

8.4.2 Floor sanitizers (e.g., BruTab or Bru Clean TbC)

8.4.3 Sterile 70% IPA – All IPA designated for use in the clean room facility must be sterile.

8.5 Sporicidal agents

8.5.1 Hydrogen peroxide with peracetic acid (e.g., Decon-Spore 200 Plus and Peridox RTU).

8.5.2 Hydrogen peroxide 6%

8.5.3 Sodium hypochlorite (e.g., Hypo-Chlor)

8.6 Deactivation/decontamination agents - EPA-registered oxidizers (e.g., Peridox RTU, Hypo-Chlor).

8.7 Cleaning shall be done using a sanitizer and sterile water, if applicable, followed by a disinfectant. The use of a sporicidal agent is required as detailed in section 6.0.

8.7.1 In the hazardous clean room, deactivation/decontamination, cleaning and disinfection are required daily in the PEC (when used), any time a spill occurs, before and after certification, any time voluntary power interruption occurs, and if the ventilation tool is moved where hazardous drugs are handled.

8.7.2 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding or low-lint and dedicated for use in the cleanroom, or ante-area. Materials shall not be removed from these areas except for disposal. In addition, cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC.

8.8 Cleaning effectiveness of the clean room is checked by periodic environmental surveys as per SOP 3.030 Environmental Monitoring of the Clean Room Facilities.

8.9 Always refer to manufacturer recommendations for appropriate dwell times and dilutions, if applicable.

8.10 Document the agent in use on the appropriate attachment.

8.11 Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used. In classified areas outside of the PEC, sterile cleaning and disinfecting agents should be used. When diluting concentrated cleaning and disinfecting agents for use outside of the PEC, sterile water should be used.

8.12 All hazardous cleaning processes performed in this SOP shall also be in compliance with SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection.

8.13 Dwell time requirements, monitoring and documentation shall be recorded on applicable attachments.

9.0 PROCEDURE

9.1 Personnel must be properly attired and gowned according to SOP 9.120 Required Garb for Clean Room Facilities Access. Additional PPE may be necessary as required by specific agents being used to clean (refer to manufacturer's recommendations).

9.2 The necessary cleaning materials are dedicated solely to cleaning each clean room facility. These materials shall be labeled as such, stored in the appropriate room of each clean room facility, and shall be kept separate from other cleaning materials.

9.3 Cleaning solutions shall be prepared as needed.

9.3.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs or manufacturers' recommendations.

9.4 Except for cleaning/disinfection of the LAFW, BSC and powder/fume hoods, cleaning of the sterile compounding area is prohibited during compounding operations within the same room.

9.4.1 Ensure all compounding operations are completed and all equipment has been removed from the LAFW, BSC or, powder/fume hood prior to cleaning.

9.4.2 The operator must clean and disinfect the exposed work surfaces (counters and walls) of the LAFW, BSC as follows:

9.4.2.1 Cleaning and disinfection, using a suitable sterile agent, shall occur on all surfaces in the ISO Class 5 PEC as outlined in section 6.0, including:

9.4.2.1.1 Daily, when compounding occurs.

9.4.2.1.2 Disinfect at least every 30 minutes when compounding Processes take 30 minutes or less. If the compounding process takes longer than 30 minutes, compounding must not be disrupted and must be disinfected immediately after.

9.4.2.1.3 After each spill.

9.4.2.1.4 When surface contamination is known or suspected.

9.4.2.1.5 Disinfection with sterile 70% IPA must occur in the PEC immediately prior to starting compounding.

9.4.3 When compounding hazardous drugs the operator must deactivate, decontaminate, clean, and disinfect the exposed work surfaces (counters and walls) of the BSC at least daily (when used) and:

9.4.3.1 Between compounding of different hazardous drugs.

9.4.3.2 After each spill.

9.4.3.3 Before and after certification.

9.4.3.4 After a voluntary power interruption occurs.

9.4.3.5 When the BSC is moved.

9.4.3.6 Disinfection with sterile 70% IPA must occur in the PEC immediately prior to starting compounding.

9.4.3.7 Disinfect at least every 30 minutes when compounding processes take 30 minutes or less. If the compounding process takes longer than 30 minutes, compounding must not be disrupted and must be disinfected immediately after.

9.5 Mop pole(s) will be cleaned before and after each use with appropriate agent(s).

9.6 The order of cleaning within the clean room facilities is as follows:

9.6.1 Non-hazardous clean room.

9.6.1.1 LAFW (ISO 5)

9.6.1.2 Buffer room (ISO 7)

9.6.1.3 Garb room (ISO 8)

9.6.1.4 Preparation room (ISO 8)

9.6.2 Hazardous clean room.

9.6.2.1 BSC (ISO 5)

9.6.2.2 Buffer room (ISO 7), may be cleaned at the same time as the garb room.

9.6.2.3 Garb room (ISO 7), may be cleaned at the same time as the buffer room.

9.6.2.4 Preparation room (ISO 8), may be cleaned at the same time as the air lock.

9.6.2.5 Air lock (ISO 8), may be cleaned at the same time as the preparation room.

9.7 A cleaning assessment will be completed initially and every six months thereafter for cleaning staff using Cleaning Assessment for Cleaning and Disinfection Procedures in the Clean Room, Attachment 12. Assessment shall be completed during a scheduled weekly or monthly clean.

9.8 Reusable PPE and garb shall be cleaned and sanitized according to SOP 4.030 Use, Verification, and Maintenance of the Tabletop Autoclave.

9.9 Daily, when compounding occurs – non-hazardous clean room.

9.9.1 Empty all waste receptacles by removing the filled plastic bag. If necessary, wipe the receptacle with cleaning solution and then disinfect, let dry and then place a clean plastic bag in the receptacle. Do not remove or relocate receptacles within the clean room facility.

9.9.2 Temperature, humidity and pressure readings shall be taken in all areas of the clean room facility and may be monitored electronically.

9.9.2.1 The humidity should be maintained in the range of 15%-60%.

9.9.2.2 The temperature shall be maintained ≤ 20°C (≤ 68°F).

9.9.2.3 For non-hazardous sterile compounding a positive pressure differential of at least 0.02 inch water column relative to all adjacent spaces is required.

9.9.2.4 Document temperature and humidity results on the Facility Control Monitoring of the Non-Hazardous Clean Room Facility, Attachment 9, as appropriate.

9.9.2.5 Document pressure results of the non-hazardous clean room on the Manometer Record – Non-Hazardous Clean Room Facility, Attachment 13.

9.9.3 The ISO 5 equipment/devices should be cleaned and disinfected in the following order (if applicable): walls, IV bar, automated compounding devices and work surface.

9.9.4 Clean and disinfect all areas at the frequency outlined in section 6.0.

9.9.5 Clean and disinfect the floors, starting at corner farthest from the door and working toward the center of the room from each sidewall toward the door. Mop heads used to clean the floor are only used in this area and then not re-used.

9.9.6 Allow all rooms and equipment to air dry, before sterile compounding resumes.

9.9.7 Cleaning shall be performed using a disinfectant or one-step cleaning and disinfecting agent followed by sterile IPA, if required by the agent's manufacturer. Non-shedding or low-lint material shall be used for cleaning.

9.9.8 Document all activities and agents used on the appropriate attachment. If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.10 Weekly requirements

9.10 Weekly

9.10.1 Perform cleaning and disinfection with a sporicidal agent on the areas outlined in section 6.0.

9.11 Monthly requirements.

9.11.1 Perform cleaning and disinfection with sporicidal agent on areas outlined in 6.0.

9.11.2 Once ISO 5 area is cleaned and disinfected as instructed in section 9.9, clean, disinfect with a sporicidal agent to the ceiling first beginning at the farthest point from the door and working toward the door.

9.11.3 Clean and disinfect with a sporicidal agent to the walls beginning with the wall farthest from the door and working toward the door. Using a wall mop, start at the ceiling and make uniform vertical strokes to floor.

9.11.4 Remove all supplies from shelving and carts. Clean and disinfect with a sporicidal agent to the storage units and supplies.

9.11.5 Clean and disinfect with a sporicidal agent to all buffer area totes, storage shelves and contents by removing contents and using a cleaning solution-soaked lint free wipe, clean the inside surfaces of the tote and the entire exterior surfaces of the tote. Allow totes to dry. Prior to replacing contents into the tote, wipe tote with sterile water to remove disinfectant residues, if recommended by the manufacturer, followed by sterile IPA. Use new wipes as needed.

9.11.6 Clean and disinfect with a sporicidal agent to all buffer area carts and contents by removing contents and using a cleaning solution-soaked lint free wipe. Clean all carts starting with the top shelf and top of post, working down to the wheels. Clean the underside of the shelves in the same manner. Use a new wipe for each cart. Allow to dry. Wipe carts with sterile water to remove disinfectant residue, if recommended by the manufacturer, followed by sterile IPA. Use new wipes as needed.

9.11.7 Clean and disinfect with a sporicidal agent to the surfaces of the sink.

9.11.8 Clean and disinfect with a sporicidal agent to the floors starting at corner farthest from the door and work toward the center of the room from each sidewall toward the door. Mop heads used to clean the floor are only used on the floor in this area and then not re-used.

9.11.9 Clean and disinfect with a sporicidal agent to the buffer area stools using a cleaning solution-soaked lint free wipe. Start at the top (seat) and work towards the floor.

9.11.10 Clean and disinfect with a sporicidal agent to the trash receptacle (interior and exterior), let dry and place a clean bag in the receptacle.

9.11.11 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.11.12 Document all activities and cleaning solution used on the appropriate Cleaning and Maintenance of the Clean Room Facility attachment (Attachments 1-8). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.12 All cleaning should be performed upon completion of compounding, so the clean room facility is always left clean. Cleaning may be performed as often as needed, but the minimum requirements are outlined in Section 6.0.

9.13 A trained sterile compounding pharmacist shall ensure the completion of tasks on a daily basis, and shall review, sign and date the appropriate attachment at the end of each month. The attachment shall be retained.

9.14 The clean room facilities and PECs shall be certified semi-annually by an approved third-party contractor according to SOP 3.030 Environmental Monitoring of the Clean Room Facilities.

9.15 In the event of a procedure deviation or error (e.g., wrong solution used, incorrect room pressure, temperature, etc.), notify the sterile compounding supervisor (designated person) and the Facilities Supervisor immediately and document accordingly.

9.15.1 In the event of temperature excursions lasting longer than 24 hours, Precision will notify the appropriate state board(s) of pharmacy, if drug components are stored in the affected area(s) (NJ).

9.16 Daily requirements – hazardous.

9.16.1 All hazardous cleaning processes shall be according to SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection.

9.16.2 Empty all waste receptacles by removing the filled plastic bag. If necessary, perform cleaning process according to SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection with appropriate agents, let dry and then place a clean plastic bag in the receptacle. Do not remove or relocate receptacles within the clean room facility.

9.16.3 Temperature, humidity and pressure readings shall be taken in all areas of the clean room facility and may be monitored electronically.

9.16.3.1 The humidity should be maintained in the range of 15%-60%.

9.16.3.2 The temperature shall be maintained ≤ 20°C (≤ 68°F).

9.16.3.3 For hazardous sterile compounding negative pressure of 0.01 to 0.03 inches of water column relative to adjacent spaces is required in the buffer and prep rooms. A positive pressure differential of at least 0.02 inch water column relative to adjacent spaces is required for the garb and air lock rooms.

9.16.3.4 Document temperature and humidity results on the Facility Control Monitoring of the Hazardous Clean Room Facility, Attachment 10, or attach printout and date and initial.

9.16.3.5 Document pressure results on Facility Control Monitoring of the Hazardous Clean Room Facility, Attachment 10.

9.16.4 The BSC equipment/devices cleaning process should be conducted in the following order (if applicable): ceiling, walls, IV bar, automated compounding devices and work surface.

9.16.5 Deactivate, decontaminate, clean, and disinfect ISO 5 work surfaces at the frequency outlined in Section 6.0.

9.16.6 Deactivate, decontaminate, and clean in use equipment and devices including high-touch areas like telephones, intercoms, and door handles.

9.16.7 Deactivate, decontaminate and clean the floors starting at corner farthest from the door and work toward the center of the room from each sidewall toward the door. Mop heads used to clean the floor are only used in this area and then not re-used.

9.16.8 Deactivate, decontaminate, clean and disinfect sink and other contact surface areas in the prep room.

9.16.9 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.16.10 Document all activities and cleaning solutions used on the appropriate Cleaning and Maintenance of the Clean Room Facility attachment. If the equipment is not in use, write "N/A" in the appropriate location on the form.

NOTE: If no hazardous compounding is occuring on that day, deactivation and decontemination step may be omitted and documented.

9.17 Weekly requirements.

9.17.1 Perform all daily cleaning activities in 9.16.

9.18 Monthly requirements.

9.18.1 Perform all cleaning activities in 9.16.

9.18.2 Once ISO 5 area's cleaning process is complete as instructed in section 9.16, clean and disinfect the ceiling first beginning at the farthest point from the door and working toward the door.

9.18.3 Clean and disinfect the walls beginning with the wall farthest from the door and working toward the door.

9.18.4 Remove all supplies from shelving and carts. Clean and disinfect with a sporicidal agent the storage units and supplies.

9.18.5 Clean and disinfect with a sporicidal agent all buffer area totes, storage shelves and contents by removing contents and using the appropriate solution-soaked lint free wipe. Wipe the inside surfaces of the tote and the entire exterior surfaces of the tote. Allow totes to dry. Follow with sterile IPA. Use new wipes as needed.

9.18.6 Clean and disinfect with a sporicidal agent all buffer area carts and contents by removing contents and using the appropriate solution-soaked lint free wipe. Begin the cleaning process with the top shelf and top of post, working down to the wheels. Continue with the underside of the shelves in the same manner. Use a new wipe for each cart.

9.18.7 Clean and disinfect with a sporicidal agent buffer area stools. Start at the top (seat) and work towards the floor.

9.18.8 Deactivate, decontaminate, clean, and disinfect the trash receptacle (interior and exterior), let dry and place a clean bag in the receptacle.

9.18.9 Clean and disinfect with a sporicidal agent to the surfaces of the sink.

9.18.10 Allow all rooms and equipment to air dry, before sterile compounding resumes.

9.18.11 The front valance of the BSC must be removed. The work tray and front valance must be deactivated, decontaminated, cleaned, and disinfected. Personnel performing this task must wear a full-face piece respirator.

9.18.12 Document all activities and cleaning solution used on the appropriate Cleaning and Maintenance of the Clean Room Facility attachment (Attachments 1-8). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.19 All cleaning processes shall be performed upon completion of compounding, so the clean room facility is always left clean. Cleaning process of the facility may be performed as often as needed, but the minimum requirement is at the end of the day after compounding.

9.20 A trained sterile compounding pharmacist shall ensure the completion of tasks on a daily basis, and shall review, sign and date the appropriate attachment at the end of each month. The attachment shall be retained.

9.21 The clean room facilities and PECs shall be certified semi-annually by an approved third-party contractor according to SOP 3.030 Environmental Monitoring of the Clean Room Facilities.

9.22 In the event of a procedure deviation or error (e.g., wrong solution used, incorrect room pressure, temperature, etc.) notify a trained sterile compounding pharmacist and the facility coordinator immediately and document accordingly.

9.22.1 In the event of temperature excursions lasting longer than 24 hours, Precision Pharmacy will notify the appropriate state board(s) of pharmacy, if drug components are stored in the affected areas (NJ).

10.0 ATTACHMENTS

10.1 Attachment 1 – Buffer Room Daily Cleaning Log

10.2 Attachment 2 – Buffer Room Weekly / Monthly Cleaning Log

10.3 Attachment 3 – Prep Room Daily Cleaning Log

10.4 Attachment 4 – Prep Room Weekly / Monthly Cleaning Log

10.5 Attachment 5 – Garb Room Daily Cleaning Log

10.6 Attachment 6 – Garb Room Weekly / Monthly Cleaning Log

10.7 Attachment 7 – Air Lock Daily Cleaning Log

10.8 Attachment 8 – Air Lock Weekly / Monthly Cleaning Log

10.9 Attachment 9 – Facility Control Monitoring of the Non-Hazardous Clean Room Facility

10.10 Attachment 10 – Facility Control Monitoring of the Hazardous Clean Room Facility

10.11 Attachment 11 – Cleaning Solution Key

10.12 Attachment 12 – Cleaning Assessment for Cleaning and Disinfection Procedures in the Clean Room

10.13 Attachment 13 – Manometer Record – Non-Hazardous Clean Room Facility

10.14 Attachment 14 – Cleaning Solution Log for Clean Rooms

11.0 HISTORY

Version Number	Review Date	Effective Date	Description of Change
1.0	10/2009 - 1/2010	1-1-2010	New SOP
2.0	11-10-2010	1-1-2011	Annual Review; See hardcopy for specific changes
2.0	12-13-2011	1-1-2011	Annual Review; No changes
3.0	1/2013 6/2013	6-14-2013	Annual Review; See hardcopy for specific changes
4.0	7/25/13	8/15/2013	See hardcopy for specific changes

5.0	3/7/2014	3/7/2014	Annual Review; See hardcopy for specific changes
6.0	3/27/2014	4/21/2014	See hardcopy for specific changes
7.0	3/16/2015	4/8/2015	Annual Review; See hardcopy for specific changes
8.0	7/2/2015	7/15/2015	See hardcopy for specific changes
9.0	7/30/2015	8/7/2015	See hardcopy for specific changes
10.	3/9/2016	4/14/2016	Annual Review; See hardcopy for specific changes
11.0	6/3/2016	7/8/2016	See hardcopy for specific changes
12.0	8/12/2016	8-19-2016	Updated for TX/NABP review; condensed Attachments
13.0	9-30-2016	10-3-2016	Updated Attachments 2, 4, 6 and 8 for recording Weekly, Monthly or Quarterly clean
14.0	10-7-2016	10-11-2016	Updated Attachments 9 and 10 (filter/BSC checks)
15.0	12-2-2016	12-28-2016	Annual Review; Extensive changes, see hardcopy for details
16.0	2-10-2017	2-13-2017	Added 9.12.3; Updated Attachments
17.0	6-28-2017	6-30-2017	Updated to remove water rinse step unless required by mfg (per BOP inspector webinar)
18.0	11-29-2017	1-24-2018	Annual Review; Updated 3.1, 6.1.1, 8.3.2, 8.4.2, 8.5, 8.7, 9.5.2.1.2, 9.9.2.2, 9.10.5, 9.14; Added 6.1.9, 8.3.3, 9.16; Updated References to current versions; Updated Attachments (added "Notes" column); Minor grammar
19.0	5-3-2018	5-21-2018	Updated 9.11.3 and 9.11.4 (moves "BSC front valance cleaning" to monthly from quarterly; Updated Attachment 2 to reflect the same; Updated Attachment 9 to include HD Pressure range
20.0	10-11-2018	12-5-2018	Updated to add new cleaners TexQ and TexTab
21.0	11-20-2019	1-13-2020	Annual Review and updated for USP <800>; see hard copy for details
Version Number	**Review Date**	**Effective Date**	**Description of Change**
22.0	7-20-2020	9-29-2020	Annual Review; Updated for NJ, NABP inspection preparation, weekly floor cleaning and USP; Added 4.9, 4.10, 6.2.2, 7.12, 7.13, 8.5.4, 8.11, 9.15.1, 9.23.1 and Attachment 14; Updated 6.2.3.1, 6.2.4.1, 6.2.6.1, 8.2, 8.5.1, 8.7, 9.5.2.1, 9.5.2.1.2, 9.9.8, 9.9.9, 9.15, 9.16.9, 9.16.10, 9.18.11, 9.23 and Attachment 11; Updated applicable Attachments to include "Weekly" requirements; Updated Attachment 13 for correct airflow direction (per SLSI); Grammar/formatting throughout
23.0	11-8-2021	2-18-2022	Annual Review; Added 5.8; Updated 6.2.1.6, 8.1, 9.8, Attachment 9 and 10 titles and Attachment 12; Grammar/formatting throughout
24.0	11-7-2022 / 1-18-2023	3-7-2023	Annual Review; Updated Precision Pharmacy to Precision Equine (Precision) throughout; Removed tacky mats throughout; replaced "contact time" with "dwell time"; removed references to soap, replaced with detergent throughout; Added dwell times to Attachments; Updated 6.1.2.1, 6.1.3.1, 6.2.3.1, 6.2.4.1, 8.9 and 9.1; Added 6.1.2.7, 6.1.3.2, 6.2.2.2 and 6.2.3.6; Updated Attachments accordingly
25.0	10-4-2023	11-1-2023	Annual Review; Updated for USP <797> effective 11-1-2023; See hardcopy and electronic file for specifics
26.0	1-10-2024	7-19-2024	Updated to replace TexTabs with BruTab; Minor grammar throughout

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Month/Year: _____

Buffer Room Daily Cleaning Log

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

	Start Time	Hoods (LAFW/BSC)		Carts		Equipment		Floors		Pass Thrus		Chairs /Stools		Trash Discarded	Trash Receptacle		Mop Pole(s) (Before/After Use)		Stop Time	No compounding
		Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials		
N/A to room																				
Date																				

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes
Decon Quat	DQ	10 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
TB1-3300	TB1	1 minute			

Notes:

Month/Year: _____ **Buffer Room Weekly/Monthly Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

Monthly PEC Pre-Filer Check:

Date: _____ Initials: _____

				Storage Shelving		Ceilings		Walls/Doors		Trash Discard-ed	Trash Receptacle		Mop Pole(s) (Before/After Use)		BSC Front Valance & Work Tray		Inside of Totes			
	Date	**Monthly**	**Start Time**	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	**Stop Time**	**Notes**
Not Applicable to Room																				
Week 1																				
Week 2																				
Week 3																				
Week 4																				
Week 5																				

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes
Decon Quat	DQ	10 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
TB1-3300	TB1	1 minute			

Notes:

Month/Year: _____ **Prep Room Daily Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

		Hoods		Countertops		Equipment		Floors		Carts		Sink		Trash Discarded	Trash Receptacle		Mop Pole(s) (before/after use)			
	Start Time	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Stop Time	Notes
Not Applicable to Room																				
Date																				

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

Month/Year: _____

Prep Room Weekly/Monthly Cleaning Log

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

	Date	Monthly	Start Time	Storage Shelving		Ceilings		Walls/Doors		Trash Discarded	Trash Receptacle		Inside of Sterile H_20 Tote/ Transportation Cart		Inside of Drawers /Cabinets		Mop Pole(s) (Before/After Use)		Stop Time	Notes
				Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Trash Discarded	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials		
Not Applicable to Room																				
Week 1																				
Week 2																				
Week 3																				
Week 4																				
Week 5																				

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

Month/Year: _____ **Garb Room Daily Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

		Floors		Pass Thrus		Chairs/Stools		Carts		Trash Discarded	Trash Receptacle		Mop Pole(s) (Before/After Use)			
	Start Time	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	**Stop Time**	**Notes**
Not Applicable to Room																
Date																

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

Month/Year: _____ **Garb Room Weekly/Monthly Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

Check One:

☐ Hazardous Clean Room

☐ Non-Hazardous Clean Room

				Storage Shelving		Ceilings		Walls/Doors		Trash Discarded	Trash Receptacle		Mop Pole(s) (Before/After Use)		Inside of Totes			
	Date	**Monthly**	**Start Time**	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	**Stop Time**	**Notes**
Not Applicable to Room																		
Week 1																		
Week 2																		
Week 3																		
Week 4																		
Week 5																		

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

Month/Year: _____ **Air Lock Daily Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

		Floors		Trash Discarded	Trash Receptacle		Mop Pole(s) (Before/After Use)			
	Start Time	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	**Stop Time**	**Notes**
Not Applicable to Room										
Date										

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

Month/Year: _____ **Air Lock Weekly/Monthly Cleaning Log**

Name and Initials of individuals involved in cleaning:

_____

_____

_____

				Storage Shelving		Ceilings		Walls/Doors		Trash Discarded	Trash Receptacle		Mop Pole(s) (Before/After Use)		Inside of Totes			
	Date	**Monthly**	**Start Time**	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	Cleaning Agent	Initials	**Stop Time**	**Notes**
Not Applicable to Room																		
Week 1																		
Week 2																		
Week 3																		
Week 4																		
Week 5																		

Reviewed By: _____ Date: _____

Cleaning Solution Dwell Times:

BruTab	BT	10 minutes	Decon Spore 200+	DS	10 minutes	TB1-3300	TB1	1 minute
TexQ	TQ	10 minutes	Peridox RTU	SPR	3 minutes	Decon Sodium Hypochlorite	DSH	10 minutes
Decon Quat	DQ	10 minutes						

FACILITY CONTROL MONITORING OF THE NON-HAZARDOUS CLEAN ROOM FACILITY

Room:_____

Month/Year: _____

Day	Temp (°C)	Humidity (%)	Pressure (inches of water)		Filter Check		Initials	Day	Temp (°C)	Humidity (%)	Pressure (inches of water)		Filter Check		Initials
			HD 1	HD 2	HD 1	HD 2					HD 1	HD 2	HD 1	HD 2	
1								17							
2								18							
3								19							
4								20							
5								21							
6								22							
7								23							
8								24							
9								25							
10								26							
11								27							
12								28							
13								29							
14								30							
15								31							
16															

Humidity Requirement: 15%-60%

Temperature Requirement: ≤20°C (≤68°F)

Pressure Requirements:

Positive Pressure: at least 0.02 inch water column relative to all adjacent spaces.

Negative Pressure: 0.01 to 0.03 inch water column relative to all adjacent spaces.

HD 1 & HD 2 Pressure : >0.40 inch water column

Reviewed By: _____ **Date:** _____

FACILITY CONTROL MONITORING OF THE HAZARDOUS CLEAN ROOM FACILITY

Room:_____ **Data Logger ID:**

Month/Year: _____

Day	Temp (°C)	Humidity (%)	BSC (Inflow / Downflow)	Pressure (inches of water) Circle +/-	Initials	Day	Temp (°C)	Humidity (%)	BSC (Inflow / Downflow)	Pressure (inches of water) Circle +/-	Initials
1				+/-		17				+/-	
2				+/-		18				+/-	
3				+/-		19				+/-	
4				+/-		20				+/-	
5				+/-		21				+/-	
6				+/-		22				+/-	
7				+/-		23				+/-	
8				+/-		24				+/-	
9				+/-		25				+/-	
10				+/-		26				+/-	
11				+/-		27				+/-	
12				+/-		28				+/-	
13				+/-		29				+/-	
14				+/-		30				+/-	
15				+/-		31				+/-	
16				+/-							

Humidity Requirement: 15%-60%
Temperature Requirement: ≤20°C (≤68°F)
Pressure Requirements:
Positive Pressure: at least 0.02 inch water column relative to all adjacent spaces.
Negative Pressure: 0.01 to 0.03 inch water column relative to all adjacent spaces.
BSC Exhaust: 1051 cfm – 1209 cfm
BSC Down flow: 55 fpm – 65 fpm

Reviewed By: _____ **Date:** _____

CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY CLEANING SOLUTION KEY

Cleaning Solution	Abbreviation	Type	Dwell Time	Expiration Dates	
				Once Mixed	Once Opened
BruTab	BT	Chlorine based	10 minutes	3 days	3 years
Decon Clean	DC	Detergent	None	60 days	60 days
Decon Glass	DG	Detergent	None	N/A	30 days
TexQ	TQ	Quat Ammonium	10 minutes	24 hours	24 months
Decon Quat	DQ	Quat Ammonium	10 minutes	30 days	30 days
Decon Spore 200+	DS	Peracetic / H_2O_2	10 minutes	30 days	30 days
Peridox RTU	SPR	Peracetic / H_2O_2	3 minutes	N/A	24 months
Sterile Isopropyl Alcohol 70%	SA	Alcohol based	None	N/A	60 days
Sterile Water	SW		None	N/A	1 shift
Decon Sodium Hypochlorite	DSH	Bleach	10 minutes	60 days	60 days
TB1-3300	TB1	Quat Ammonium/ Ethyl Alcohol	1 minute	N/A	6 months
Liquinox	LQ	Equipment/Instrument detergent	N/A	2 weeks	24 months from end of month of manufacture

Note:
S = Sterile - By placing an "S" in front of the abbreviations, it indicates the solution was sterile.

Cleaning Assessment for Cleaning and Disinfection Procedures in the Clean Room

General:

_____ Follows proper garbing and gloving procedures.

_____ Uses proper PPE for the cleaning solutions being used.

_____ Prepares correct concentration of disinfectant solution according to manufacturer's instructions.

_____ All surfaces of the room are being saturated for the proper dwell time per the cleaning agent being used.

Monthly Tasks:

_____ Cleans ISO 5 areas first in the following order (if applicable): walls, IV bar, automated compounding devices, and work surface.

_____ Starts cleaning in buffer room (cleanest) and works towards prep room/air lock (dirtiest).

_____ Cleaning of ceilings is started at the wall opposite the room entry door and is cleaned toward the door to the next room.

_____ Cleaning of walls is started at the wall opposite the room entry door and is cleaned toward the door to the next room.

_____ All vertical surfaces are cleaned with continuous strokes from the top to the bottom.

_____ All areas of hoods are cleaned including the entire hood exterior and underneath surfaces.

_____ All chairs are cleaned from the top of the chair to the wheels.

_____ All carts/shelves are cleaned with contents being removed first. Starting with the top shelf and top of post clean the carts working down toward the wheels. Cleans the underside of shelves in a similar manner. Uses a new wipe for each cart. Allows carts to dry. Wipes carts with sterile 70% IPA (or sterile water, if recommended by manufacturer) to remove disinfectant residue. Uses new wipe as needed.

_____ All trash receptacles are cleaned inside and out.

_____ Cleans all counters and work surfaces.

_____ Floors are mopped with designated floor mop starting at the wall opposite the room entry door; floor surfaces are mopped in even strokes toward the operator.

_____ Cleans all buffer area totes and storage shelves by removing contents. Cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows tote to dry. Prior to replacing contents into the tote, wipes tote with sterile water, if recommended by manufacturer, to remove disinfectant residue. Uses new wipe as needed.

_____ All remaining residues on surfaces are removed with sterile water and sterile 70% IPA, with the final step always being sterile 70% IPA, if needed.

_____ Correct documentation has been completed, signed, and dated.

All steps were followed per SOP 3.020 Yes ☐ No ☐

Date:_____ Time:_____

Notes:_____

_____

_____

The person being assessed is immediately informed of all unacceptable activities and is informed of specific corrections to be made.

Printed Name of Person Assessed: _____

Signature of Person Assessed: _____Date: _____

Signature of Pharmacist: _____ Date: _____

MANOMETER RECORD – NON-HAZARDOUS CLEAN ROOM FACILITY

Month/Year: _____

Positive pressure differential must be at least 0.02 inch water column relative to adjacent spaces.

Day	Time	Manometer 1 buffer room to ambient	Manometer 2 prep room to ambient	Manometer 3 garb room to ambient	Manometer 4 garb room to prep room	Manometer 5 buffer room to garb room	Initials	Notes
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
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29								
30								
31								

Reviewed By: _____ Date: _____

Cleaning Solution Log for Clean Rooms

Date	Type of Cleaning Solution	Qty of Cleaning Concentrate	Qty of Water	Total Qty Made	Notes	CLK/RPH Initials
						/
						/
						/
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Dilutions Guide

	Amount of Concentrate	Amount of Sterile Water	Expiration Date (once mixed)
BruTab	1 tablet	960ml (32oz)	3 days
Decon Quat	1/2 oz	1 Gallon	30 days
Decon Clean	1 oz	1 Gallon	60 days
Liquinox	10ml	1000ml	2 weeks

Reviewed by: _____ Date: _____

WEDGEWOOD PHARMACY LLC	
TITLE: DEACTIVATION, DECONTAMINATION, CLEANING AND DISINFECTION	
SOP NUMBER: 13.020	**VERSION NUMBER: 5.0**
Authorized By:	Date:
Written By: Rachel Taggs	Date: 11-9-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for deactivating, decontaminating, cleaning, and disinfecting the hazardous drug compounding and storage areas at Wedgewood Pharmacy, Bakersfield ("Bakersfield").

2.0 SCOPE

2.1 This procedure applies to the Bakersfield hazardous compounding and storage areas under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopela <800>, <797> and <795>.

3.0 RESPONSIBILITY

3.1 On duty pharmacists, with the assistance of the Warehouse Supervisor, shall supervise this procedure or document that another staff member has been assigned to this task.

3.2 All personnel in Bakersfield are responsible for following this procedure.

4.0 REFERENCES

4.1 USP current version <800> "Hazardous Drugs – Handling in Healthcare Settings"

4.2 USP current version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP current version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

4.4 Peridox RTU ACA018, HCA001

4.5 American Society of Health-System Pharmacists (ASHP); Guidelines on Handling Hazardous Drugs October 17, 2018

5.0 DEFINITIONS

5.1 Cleaning – the process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products. (USP <800>)

5.2 Deactivation – treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent. (USP <800>)

5.3 Decontamination – inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means. (USP <800>)

5.4 Detergent – cleaning solution used to remove dirt and chemical residue.

5.5 Disinfectant –a chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores. . (USP <797>)

5.6 Hazardous drug (HD) – any drug identified by at least one of the following six criteria: carcinogenicity, teratogencity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity (USP <797> and <800>). Bakersfield's HDs are listed

on Wedgewood Pharmacy, Bakersfield Hazardous Drug List, Attachment 1, SOP 13.010 Hazardous Communication Program, or equivalent.

5.7 PEC – primary engineering control.

5.8 PPE – personal protective equipment.

5.9 IPA – isopropyl alcohol

6.0 FREQUENCY

6.1 Frequency of cleaning shall be performed according to frequency outlined in SOPs 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent, and 3.050 Cleaning and Maintenance of the Non-Sterile Compounding and Storage Areas, or equivalent.

7.0 EQUIPMENT & SUPPLIES

7.1 PPE

7.2 Lint free wipes.

7.3 PeridoxRTU

7.4 Sterile and non-sterile IPA.

7.5 Detergent

7.6 Water

7.7 Hood cleaning tools.

7.8 Mop poles

7.9 Mop pads

8.0 GENERAL INFORMATION

8.1 All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected.

8.2 All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in hazardous drug handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination. All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns. Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used.

8.3 The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of hazardous drug contaminant(s), location, and surface materials. The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading hazardous drug residue.

8.4 Deactivation

8.4.1 Deactivation renders a compound inert or inactive. While deactivating a hazardous drug is preferred, no single process or agent has been found to deactivate all currently available hazardous drugs from different surface materials. Residue from deactivation must be removed by decontaminating the surface. The ultimate goal should be complete surface decontamination.

8.4.2 Products that have known deactivation properties (EPA-registered oxidizing agents that are appropriate for the intended use) should be used when possible. There is no one proven method for deactivating all compounds.

8.4.3 Manufacturer or supplier directions shall be followed when using the deactivating agent(s) (e.g., how to apply, if a neutralizer is needed, contact time, etc.)

8.5 Decontamination

8.5.1 Decontamination occurs by inactivating, neutralizing, or physically removing hazardous drug residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned. Decontamination may also be considered the combined process of cleaning and deactivating.

8.5.2 The work surface of the PEC must be decontaminated between compounding of different hazardous drugs. The PEC must be decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary power interruption occurs, and if the ventilation tool is moved.

8.5.3 The area under the work tray of the PEC should be deactivated, decontaminated, and cleaned at least monthly, if applicable.

8.5.3.1 Deactivate, decontaminate, and clean as much as possible of the PEC surfaces before accessing the area under the work tray. When deactivating, decontaminating, and cleaning under the work tray of the PEC, the containment airflows are compromised by opening the cabinet. To provide protection to the employee performing this task, respiratory protection may be required.

8.5.4 Manufacturer or supplier directions shall be followed when using the decontaminating agent(s) (e.g., how to apply, if a neutralizer is needed, contact time, etc.)

8.6 Cleaning

8.6.1 Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.

8.6.2 Cleaning agents used on compounding equipment should not introduce microbial contamination.

8.6.3 No cleaning step may be performed when compounding activities are occurring.

8.6.4 Manufacturer or supplier directions shall be followed when using the cleaning agent(s) (e.g., how to apply, if a neutralizer is needed, contact time, etc.)

8.7 Disinfection

8.7.1 Disinfection is a process of inhibiting or destroying microorganisms.

8.7.2 Before disinfection can be adequately performed, surfaces must be cleaned.

8.7.3 Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.

8.8 One agent may be used to satisfy all or multiple steps if, according to the manufacturer or supplier, the agent meets the criteria listed in the table below.

Cleaning Steps		
Cleaning Step	**Purpose**	**Example Agents**

Deactivation	Render compound inert or inactive.	As listed in the hazardous drug labeling or other agents which may incorporate Environmental Protection Agency – registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.).
Decontamination	Remove hazardous drug residue.	Materials that have been validated to be effective for hazardous drug decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite.
Cleaning	Remove organic and inorganic material.	Germicidal detergent
Disinfection (for sterile compounding)	Destroy microorganisms.	Environmental Protection Agency-registered disinfectant and/or sterile alcohol as appropriate for use.

9.0 PROCEDURE

9.1 Before beginning the deactivation, decontamination, cleaning, and disinfection process for any reason (e.g., regularly scheduled process or a spill) personnel shall be properly garbed according to the SOP applicable to the procedure.

9.2 When beginning the process of deactivation, decontamination, cleaning, and disinfection always work through areas as outlined in SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent, or SOP 3.050 Cleaning and Maintenance of the Non-Sterile Compounding and Storage Areas, or equivalent.

9.3 Deactivation and decontamination.

9.3.1 Deactivation shall be achieved by rendering the hazardous drug inert.

9.3.2 For hazardous drug powder residue, wet a dry lint free wipe with an EPA-registered oxidizer (e.g., PeridoxRTU) to remove the hazardous drug. For liquid hazardous drug residue, remove the liquid residue with a dry wipe and then deactivate according to powder residue directions. Discard wipes according to SOP 9.090 Proper Disposal of Pharmacy Waste, or equivalent.

9.3.3 The deactivating agent should not be sprayed but poured on a wipe or use a pre-wet wipe to avoid aerosolizing the hazardous drug.

9.3.4 Decontamination occurs when a deactivated hazardous drug is transferred from a non-disposable surface to a disposable one and removed from the area (i.e., wiping the deactivating agent from the work surface and the hazardous drug is transferred to the wipe).

9.4 Cleaning

9.4.1 No cleaning step shall be performed while compounding activities are occurring.

9.4.2 Saturate a new dry wipe with a germicidal detergent (e.g., PeridoxRTU).

9.4.3 Wipe the surface with the saturated wipe, utilizing overlapping, unidirectional strokes in an order applicable to the area or equipment being cleaned.

9.4.4 Reapply agent to the existing or a new wipe as needed to thoroughly clean the entire surface or area. Allow the agent to sit for the appropriate contact time for germicidal or sporicidal action.

9.4.5 To remove residue, wipe surface with water or IPA after appropriate contact time.

9.4.6 For sterile compounding, proceed to 9.5.

9.5 Disinfection, if applicable, for sterile compounding area(s) and equipment only.

9.5.1 Once area or surface to be cleaned has been saturated with wet wipe, allow the surface to remain wet for the specified contact time according to the manufacturer for antimicrobial or sporicidal activity.

9.5.2 After the specified contact time has lapsed, complete the process by wiping the area or surface with a new wipe wetted with sterile 70% IPA.

9.6 All hazardous drug cleaning materials must be discarded as hazardous waste according to SOP 9.090 Proper Disposal of Pharmacy Waste, or equivalent.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Review Date	Date Effective	Description of Change
1.0	11-4-2019	1-22-2020	New SOP.
2.0	8-7-2020	9-22-2020	Annual Review; Added 5.9, 7.7, 7.8, 7.9; Grammar/formatting throughout
3.0	11-9-2021	1-10-2022	Annual Review; Updated 5.1 – 5.3 and 9.2; Grammar/formatting throughout
4.0	12-14-2022	2-16-2023	Annual Review; Updated Precision Pharmacy to Precision Equine (Precision) throughout; Updated 9.5.1 and 9.5.2; Grammar/formatting
5.0	11-30-2023 10-1-2024	10-3-2024	Annual Review; Updated Precision Equine to Wedgewood Pharmacy throughout; Updated Warehouse Supervisor title; Updated 5.5 and 5.6; Added "or equivalent" to Bakersfield SOPs to allow for SOP integration

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WEDGEWOOD PHARMACY LLC	
TITLE: COUNSELING OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 5.040	**VERSION NUMBER: 22.0**
Authorized By:	Date:
Written By: Rachel Taggs/Shauna Doherty	Date: 4-14-2022
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 This procedure is intended to ensure that the patient's owner/caregiver or prescriber understands how to use prescribed compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at Wedgewood Pharmacy LLC, Bakersfield ("Wedgewood").

3.0 RESPONSIBILITY

3.1 The pharmacist on duty shall supervise this procedure.

4.0 REFERENCES

4.1 SOP 5.010 Patient Medication Profiles

4.2 Current Lawbook for Pharmacy, California; Sections 1707.6 Notice to Consumers and 1707.2 Duty to Consult and 1751.6 Sterile Compounding Consultation; Training of Sterile Compounding Staff

4.3 Current Illinois State Board of Pharmacy Rules 1330.700 – Patient Counseling

4.4 Current Utah Pharmacy Practice Act; Rule R156-17b-608 Delivery Via United States Postal Service, Licensed Common Carrier, or Supportive Personnel.

4.5 Current Texas Board Rule 291.3 Required Notifications

4.6 Current Wisconsin Administrative Code; Pharmacy Examining Board; Chapter 7, Pharmacy Practice; Section 7.08 Patient consultation

4.7 Current New Jersey Professions and Occupations; New Jersey Pharmacy Practice Act, Chapter 45:14; Section 45-14-67.6 Advising patients on the proper disposal of unused prescription drugs and controlled dangerous substances; dispensing prescription drugs or Requirements for pharmacies conceming information provided to patients.

4.8 Current Connecticut Code; Title 2, Chapter 400j, Section 20-635 Prescription Error Reporting. Definitions. Informational signs and statements. Regulations. Nondisclosure of records.

4.9 Current Oregon Administrative Rules (OAR), Chapter 855, Division 41 Operation of Pharmacies 855—041-1131 Prescription Reader Availability

4.10 Poison Prevention Packaging Act

4.11 Additional state and federal pharmacy regulations/laws, as applicable.

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 According to CCR 1707.2 Duty to Consult, a pharmacist shall provide oral consultation to his or her patient or patient's agent in all settings when a prescription is dispensed by the pharmacy.

6.1.1 Upon request.

6.1.2 Whenever the pharmacist deems it warranted in the exercise of his or her professional judgement.

6.1.3 Whenever the prescription drug has not been dispensed to a patient; or

6.1.4 Whenever a prescription drug not previously dispensed to a patient In the same dosage form, strength or with the same written directions.

7.0 EQUIPMENT & SUPPLIES

7.1 Compounded preparation.

7.2 Patient advisory leaflet (PAL) – informational sheet that address topics specific to a medication or class of medications.

7.3 Wedgewood Pharmacy Bakersfield Information Sheet, Attachment 1.

8.0 GENERAL INFORMATION

8.1 Patient consultation may include and is not necessarily be limited to:

8.1.1 Making appropriate recommendations regarding medication therapy management and adherence;

8.1.2 Obtaining a medication profile, allergy and pertinent medical history from the patient seeking consultation;

8.1.3 Evaluating the patient's medication profile, in conjunction with applicable allergies and disease states, in order to determine appropriate interventions and/or referrals;

8.1.4 Ensuring the patient understands the counseling points explained;

8.1.5 Establishing contact with the patient's provider in the event a referral or intervention in therapy is needed;

8.1.6 Performing a full review of the information obtained from the patient, looking for issues pertaining to non-compliance, inappropriate therapies or prescribing practices; over/underutilization, and interactions with other medications, allergies, disease-states, or supplements; and

8.1.7 Recording pertinent information related to the information obtained from the patient and the counseling performed in the patient's profile or the pharmacy's counseling log, if applicable.

6.2 Pharmacists involved in patient consultation shall complete the appropriate training requirements for their position according to SOP 2.060 Compounding Pharmacist Qualification.

8.3 Wedgewood's website shall clearly provide information regarding pharmacist consultation and provide a phone number a patient may use to request pharmacist consultation.

8.4 All mailed prescriptions shall receive Wedgewood Pharmacy Bakersfield Information Sheet, Attachment 1, advising of their right to consultation.

8.5 All prescriptions will be dispensed with the corresponding PAL.

8.6 Wedgewood Pharmacy Bakersfield Information Sheet, Attachment 1, advises patient owner/caregivers that medications may be dispensed without a child resistant safety cap.

9.0 PROCEDURE

9.1 When oral consultation is provided, whether in person or by telephone, it shall include at least the following:

9.1.1 Directions for use and storage and the importance of compliance with directions; and

9.1.2 Precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

9.2 Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

9.2.1 The name and description of the medication;

9.2.2 The route of administration, dosage form, dosage, and duration of drug therapy;

9.2.3 Any special directions for use and storage;

9.2.4 Precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

9.2.5 Prescription refill information;

9.2.6 Therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

9.2.7 Action to be taken in the event of a missed dose.

9.3 Notwithstanding the requirements set forth in subsection 9.1 and 9.2, a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation. (9.1 through 9.3; CCR Sections 1707.2 Duty to Consult.)

9.4 The patient owner/caregiver shall be counseled on the appropriate use of the compounded preparation, any adverse effects the patient should be aware of and any additional information relevant to the compounded preparation, as outlined in 9.1 and 9.2 above.

9.4.1 Consultation shall include the proper use, storage, handling, and disposal of sterile injectable preparations, if applicable. (CCR 1751.6[a])

9.5 Prescription refills shall be counseled upon request or when a pharmacist deems necessary.

9.6 When physically present, the patient owner/caregiver shall be counseled in a private or semi-private area such that sensitive patient information may be retained and so the pharmacist has access to a computer for patient information.

9.7 Special instructions and information shall be distributed with the preparation if available and/or upon request. (Example: Topi-Click Micro Transdermal applicator instructions, Attachment 4)

9.8 Patient owner/caregiver that have received their preparation via mail will receive Wedgewood Pharmacy Bakersfield Information Sheet, Attachment 1, which advises patient owners/caregivers of at least the following:

9.8.1 Their right to request consultation. (CCR 1707.2)

9.8.2 Hours of availability and a toll-free telephone number from which they may obtain oral consultation from a pharmacist who has ready access to the patient's record. (CCR 1702)

9.8.3 Information on the medication's storage and stability.

9.8.4 How to dispose of expired or unused medications. (WI 7.08, NJ 45:14-67.6)

9.8.5 How to obtain a copy of Wedgewood's Notice of Privacy Practices.

9.8.6 How to file a complaint or grievance and who to contact at the pharmacy. (WI 7.08)

9.9 Patient owners/caregivers that have received their sterile injectable preparation via mail and require instruction regarding the proper use should be instructed via phone or advised to contact their veterinarian.

9.9.1 Veterinarians are the main source of hands-on training for the administration of injectable medications to animal patients.

9.9.2 Supplemental written and/or pictorial information sheets for intra-muscular injections should be provided in the package and upon request by the animal caregiver/owner or prescriber (Attachment 2).

9.10 Illinois patient owner/caregiver will receive, IDFPR – Provided Patient Notification, Attachment 3, with mailed prescriptions as required according to Illinois pharmacy rules (1330.770 – Patient Counseling).

9.11 Texas patient owners/caregivers will receive Notification to Texas Owners/Caregivers, Attachment 5, with prescriptions delivered to patients at their residence or other designated location as required according to Texas rules (291.3 Required Notifications).

9.12 Wisconsin patient owners/caregivers will receive Wisconsin Patient Consultation Notification, Attachment 6, with mailed prescriptions according to Wisconsin Pharmacy rules (7.08 Patient consultation).

9.13 New Jersey patient owners/caregivers will receive New Jersey Patient Advisory, Attachment 7, with mailed prescriptions according to New Jersey Pharmacy law (75-14-67.6).

9.14 Connecticut patient owners/caregivers will receive Connecticut Patient Advisory, Attachment 8, with mailed prescriptions according to Connecticut Code; Title 2, Chapter 400j, Section 20-635 Prescription Error Reporting. Definitions. Informational signs and statements. Regulations. Nondisclosure of records.

9.15 Oregon patient owners/caregivers will receive Oregon Prescription Reader Advisory, Attachment 10, with mailed prescriptions according Oregon Administrative Rules (OAR), Chapter 855, Division 41 Operation of Pharmacies 855—041-1131 Prescription Reader Availability

9.16 A pharmacist will be available by telephone after hours (24/7), as required by various state regulations.

9.16.1 Wedgewood's after hours voice message will provide instructions for contacting the on-call pharmacist.

9.16.2 A pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week. (CCR 1707.2)

9.17 In the event of a medical emergency (an event outside routine consultation), patient owners/caregivers will be advised to contact their veterinarian.

9.17.1 Wedgewood's after hours automated recording will advise patient caregivers/owners to contact their local veterinarian or veterinarian hospital in case of medical emergency.

9.18 When a pharmacist performs counseling it shall be documented on the patient's profile.

9.19 In the event of a limited English-speaking patient owner/caregiver or prescriber, Wedgewood will provide translation services via phone using Language Line at 888-808-3008 (access code 30928072).

9.20 Upon filling an initial prescription with Wedgewood every attempt will be made to advise the patient owner/caregiver that Wedgewood's medications may be dispensed without a child resistant safety cap. Notice of Non-Child Resistant Packaging, Attachment 9 should be included with the first fill medication delivery.

10.0 ATTACHMENTS

10.1 Attachment 1 – Wedgewood Pharmacy Bakersfield Information Sheet

10.2 Attachment 2 – An Owner's Guide to Administering Intramuscular Injections for Horses

10.3 Attachment 3 – IDFPR - Provided Patient Notification (IL BOP)

10.4 Attachment 4 – Topi-Click Micro Transdermal applicator instructions

10.5 Attachment 5 – Notification for Texas Owners/Caregivers

10.6 Attachment 6 – Wisconsin Patient Consultation

10.7 Attachment 7 – New Jersey Patient Advisory

10.8 Attachment 8 – Connecticut Patient Advisory

10.9 Attachment 9 – Notice of Non-Child Resistant Packaging

10.10 Attachment 10 – Oregon Prescription Reader Advisory

10.11 Attachment 11 – GFI Labeling Insert

11.0 HISTORY

Version Number	Review Date	Effective Date	Description of Change
1.0	10-2009-12/2009	12-2-2009	New SOP
2.0	12-30-2010	1-1-2011	Annual Review; See file for changes
3.0	12-20-2011	12-20-2011	Annual Review; See file for changes
4.0	1-2013	6-14-2013	Annual Review; See file for changes
5.0	2-14-2014	2-14-2014	See file for changes
6.0	5-20-2014	5-21-2014	See file for changes
7.0	7-11-2014	7-14-2014	See file for changes
8.0	2-27-2015	3-19-2015	Annual Review; Amended Attachment 1
Version Number	**Review Date**	**Effective Date**	**Description of Change**
9.0	5-5-2015	5-8-2015	Updated procedure to reflect 2015 CA Law
10.0	7-24-2015	7-27-2015	Added Attachment 2
11.0	8-14-2015	8-24-2015	Added reference to reporting AE on Attachment 1
12.0	6-23-2016	6-30-2016	Annual Review; Added Section 8.0; Updated Attachment 1
13.0	10-10-2016	10-11-2016	Updated Attachment 1; TX law review

13.0	5-11-2017	10-11-2016	Annual Review; No Changes
14.0	2-22-2018	3-8-2018	Annual Review; Updated References to current (2018) versions; Minor grammar/language; Added 9.8.6, 9.10, Attachment 3; 9.8.6 and Attachment 2 updated for PCAB
15.0	3-6-2019	6-18-2019	Annual Review; Updated References to current versions; Updated 6.1, 7.3, 8.1.6, 8.1.7, 9.7, 9.13; Updated Attachment 1; Added Attachment 4; Minor grammar/formatting throughout
16.0	3-18-2020	5-15-2020	Annual Review; Updated 1.1, 7.2 and Attachment 1; Added 4.4; Grammar/formatting throughout
17.0	7-20-2020	7-27-2020	Reviewed for NABP inspection preparation; Updated 7.2 and Attachment 4; Added 8.4, 8.5 and 9.13
18.0	9-14-2020	10-6-2020	Reviewed for TX law review; Added 4.5, 9.11 and Attachment 5
19.0	1-25-2021	2-5-2021	Reviewed for NJ and WI law reviews added Attachments 6 and 7 and language pertaining to each within SOP.
20.0	3-31-2021	4-27-2021	Annual Review and updated for Texas; Updated Attachments 1 and 5; Grammar throughout
21.0	4-14-2022	5-27-2022	Annual Review; Updated 4.2, section 6.0, 9.4.1, and 9.8.2; Added 4.9, 9.14, 9.15.2 and Attachment 8; Grammar/formatting throughout
22.0	1-31-2023 2-24-2023	6-17-2024	Annual Review; Updated name to Wedgewood throughout; Added 8.6 and updated Attachment 1 for safety caps; Added 4.10, 4.11, 9.15 and 9.20; Updated Attachment 1 for PCAB standard TCRX7-N for HD spill

Remainder of this page intentionally left blank

Wedgewood Pharmacy Bakersfield Information Sheet

Inspect all medication carefully within 24 hours of receipt to ensure it is correct and undamaged.

- Please contact the pharmacy immediately upon receipt if:
  - The package or preparation appears damaged
  - The controlled ROOM TEMPERATURE indicator has entered the "Prolonged" range (pink or red in color) OR
  - The REFRIGERATED temperature indicator has entered the "Moderate" range (pink or red in color)

You have the right to receive consultation from a pharmacist. If you wish to receive a consultation regarding your medication, please contact the pharmacy.

A pharmacist may be reached during normal business hours Monday-Friday 8:15AM-5:15PM (PST) or after hours for emergency consultation.

This medication has been compounded for your animal as prescribed by your veterinarian. This medication should only be given to the animal for which it was prescribed. Wedgewood cannot accept returned medications.

Storage and Stability:

- Store the medication at the recommended storage temperature provided on the label. Minimize exposure to extreme temperatures and humidity.
- Failure to store preparations at the recommended temperature may subject the medication to degradation.
- Before administering, examine the medication for signs of instability or degradation which may include change in color, odor, consistency, or appearance.

How to dispose of unused or expired medication:

- Mix medication with an unpalatable substance such as kitty litter or used coffee grounds.
- Place the mixture in a disposable container with a lid, or a sealed plastic bag.
- Conceal or remove any personal or drug information on original prescription container before throwing it away in your household trash.
- The sealed container or bag with drug mixture and the empty prescription containers can now be placed in the trash.
- **Do Not** flush unused medication or pour down a sink or drain.
- For more information on disposal of unused medications please contact the pharmacy or visit "How to Dispose of Unused Medicines" https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know.

Controlled Substance Prescriptions:

- If you are receiving a controlled substance prescription for an animal under your care, be advised your information may be shared with governmental bodies for administration purposes as required by law.

Questions or concerns?

- To report any adverse events, complaints or grievances related to compounded preparation(s), please contact the pharmacy immediately to speak to a pharmacist. Wedgewood will conduct an investigation and keep the caregiver and veterinarian informed of the investigation progress.

Notice of Privacy Practice is available on our website www.precisionpharmacy.com. Please contact the pharmacy if you would like a copy to be mailed to you.

Written information about this prescription has been provided to you. Please read this information before you administer the medication.

Many of Wedgewood's medications are not dispensed with child resistant safety ceps. By using Wedgewood, you agree to waiving the safety cap.

661-377-3333 or 877-734-3338

SOP 5.040 - Attachment 1 - Version 22.0

Wedgewood Pharmacy Bakersfield Information Sheet

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661-377-3333 or 877-734-3338

SOP 5.040 - Attachment 1 - Version 22.0

Step 4: Needle Disposal

Used Needle Disposal

- Used needles should be placed in puncture-resistant, sharps containers immediately after use.
- Keep sharps containers out of reach from children or animals.
- Contact local facilities for disposal sites or services. These may include:
  - Community drop-off collection areas
  - Home needle destruction services
  - Residential "special waste pickup services"
  - Household "hazardous waste centers"

What NOT to Do

- Reuse needles
- Place used needles in the garbage
- Flush needles down the toilet
- Place needles in recycling bins

Questions?

Contact Your Prescribing Veterinarian or Contact Us:

Wedgewood Pharmacy LLC
5301 Young St.
Bakersfield, CA 93311

877-734-3338

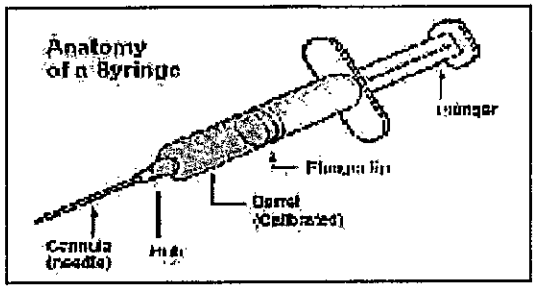
info@precisionpharmacy.com

wedgewood

An Owner's Guide to Administering Intramuscular Injections for Horses

This is a quick, step-by-step reference for administering IM injections to horses. These guidelines are intended to supplement directions given by your veterinarian. For further instructions or training please contact your prescribing veterinarian.

- **Step 1: Consult Your Veterinarian**
- **Step 2: Preparation of Injection Site**
- **Step 3: Administration**
- **Step 4: Needle Disposal**



Step 1: Consult Your Veterinarian

Consultation

- Administering IM injections is a common procedure but improper technique can lead to serious infections or abscesses.
- Discuss signs and symptoms with your veterinarian of adverse drug reactions and what to do if they occur.

Caregiver Safety

- If you are unsure how the horse will react to an injection, it is best to untie the horse and have someone else hold the lead line. A tied horse may panic with the constraint resulting in handler injury.
- If the horse moves during the injection, it is best to move with the animal and then finish the injection after the horse has calmed down.

Medication Precautions

- Always check the medication label for the correct drug name, dosage, expiration and storage instructions.
- Never mix different medications into the same syringe unless specifically instructed.
- Wear gloves while administering the injection since some medications can be absorbed through human skin.

Step 2: Preparation of Injection Site

Needle Selection

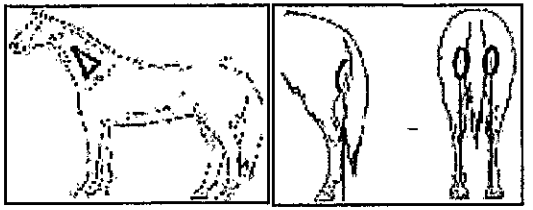
- Use sterile individually packaged syringes.
- Never reuse a needle since this can spread diseases and cause infections.
- Needle gauge selection will depend on the thickness of the medication to be administered. Consult your veterinarian or pharmacist if you are unsure.

Medication Preparation

- Remove the needle cap but do not touch the needle shaft.
- Draw up a volume of air equal to the dose volume.
- Swab the top of the vial with alcohol and insert needle into vial.
- Tilt the vial upside down and inject some air into the bottle. Continue to move plunger back and forth until all volume is pulled up in syringe.
- Pull the needle out of the vial and hold with the needle pointing up. Tap the barrel to move all air bubbles to the top and push plunger up to remove any remaining air. Recap the needle.

Injection Site

- Choose a large muscle mass area that will facilitate drug absorption and also ensure handler safety (common areas pictured below).
- Remove any dirt from the selected area and swab the skin with an alcohol-soaked pad.



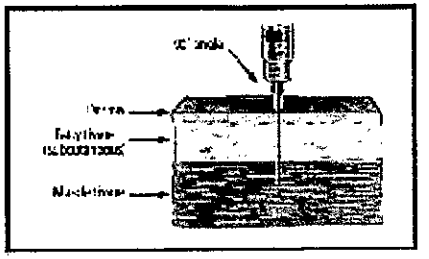
Step 3: Administration

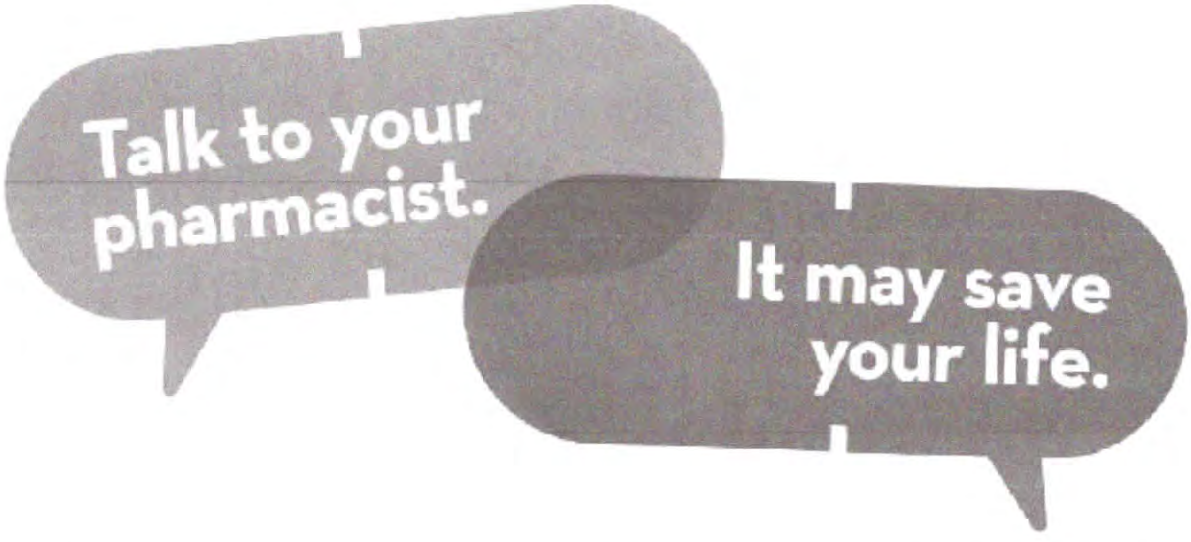
Injection Administration

- Pinch the skin next to the injection site. This will distract the animal and help with the needle insertion.
- Insert the needle perpendicular to the skin (at a 90° angle) and push the needle into the muscle until the hub touches the skin. This should be done quickly to ease the pain for the horse.
- Pull back slightly on the plunger before giving the injection to ensure the needle is not in a blood vessel.
- If blood enters the syringe or collects at the hub, pull the needle out and replace it with a new sterile needle to start the procedure again.
- Push down on the plunger slowly to inject all the medication from the syringe into the muscle.

Adverse Reaction Observation

- After the injection has been administered, observe the horse for at least 30 minutes. Signs and symptoms of an anaphylactic reaction usually happen immediately. This is a serious reaction and your veterinarian should be contacted immediately.
- Other symptoms of allergic reactions may include hives, site swelling, increased breathing rate or agitation. If this occurs, stop using the medication and contact your veterinarian.





Illinois law requires the pharmacist talk to you about any new or changed prescriptions.

Education ensures safe and effective use of your medications, reducing the chances of a serious interaction.

If you receive prescriptions by mail, you may contact the pharmacist at the number provided on your order.

If the pharmacist fails to discuss any new or changed prescriptions with you, please contact the state regiulatory authority.

Department of Financial and Professional Regulation
Division of Professional Regulation
Complaint Intake Unit
100 West Randolph Street, Suite 9-300
Chicago, IL 60601
Phone: (312) 814-6910
www.idfpr.com

Topi-CLICK

Topical Dosing Applicators

by DOSELOGIX

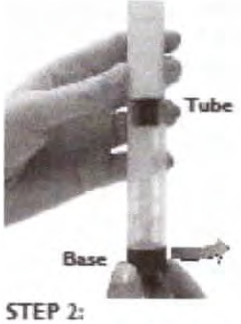
Topi-CLICK MICRO™ User Instructions

Topical Micro-dosing Application

- Automated, metered topical dosing provides an accurate and consistent dose every time
- Audible, Tactile and Visual CLICKs indicate measure of dose (no need to manually mark dose)
- Innovative triad-shape allows for precision handling
- Built-in REFILL Badge helps patients reorder medication on-time

Pet Owner Approved MICRO

STEP 1:
Unscrew the cap of the Topi-CLICK® Micro™ and set aside for recapping after use.



STEP 2:
Holding the Micro™ in an upright position, turn/CLICK the **Base** the number of CLICKs or mLs specified on the prescription label. Use the Audible, Tactile and Visual CLICK points of the triad-shaped **Base** as dosing indicators. Be sure to align Base with the Triad Tube to ensure dose is fully dispensed.

STEP 3:
Apply topical medication with built-in applicator as directed by physician or pharmacist. Continue rubbing until preparation is completely absorbed into the skin. **IMPORTANT:** The built-in applicator lessens the risk of transference to unintended areas. No need to use your fingertips to apply medication.

STEP 4:
Screw on cap after each dose to prevent evaporation. Be sure cap is secured completely.

Each turn/Click of the base dispenses 0.05 mL of medication accurately.

Innovative TRIAD Shape Allows Precision Application Control

The Refill Badge™ reminder system helps patients reorder in a timely manner.

When the **TOP** black line of the **Plunger** reaches the embossed line below the word "REFILL" approximately 32 CLICKs are left. Approximately 12 CLICKs remain at the line above the word "REFILL".

Note: Graduated Marks are for pharmacy filling purposes only. Follow instructions on prescription label before use. Topi-CLICK® Micro™ is not re-fillable.

Made of FDA grade materials | Phthalate free | blocks UV and is Recyclable ♺.

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SOP 5.040
Version 22.0
Attachment 4

Wedgewood Pharmacy
Bakersfield
Toll-Free: 877-734-3338 Local:
661-377-3333
Fax: 661-377-3333
info@precisionpharmacy.com

wedgewood

Notification for Texas Owners/Caregivers

Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have any questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at:
(877) 734-3338

Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at:

Texas State Board of Pharmacy
George H. W. Bush State Office Building
1801 Congress Ave, Suite 13.100
Austin, TX 78701-1319
https://www.pharmacy.texas.gov/
Phone: (512) 305-8000
Complaints: (800) 821-3205 (option 1)

Informaciòn escrita sobre esta receta se ha propocionado para usted. Por favor lea esta informaciòn antes de que usted se tome el medicamento. Si usted tiene preguntas referentes a esta receta, un farmacèutico està disponible durante horas de oficina normales para contestar estas preguntas al:
(877) 734-3338

Quejas contra la practica de la farmacia pueden ser reportadas al:
Concilio Farmacia Del Estada De Texas
George H. W. Bush State Office Building
1801 Congress Ave, Suite 13.100
Austin, TX 78701-1319
https://www.pharmacy.texas.gov/
Teléfono: (512) 305-8000
Quejas: (800) 821-3205 (opción 1)

SOP 5.040
Version 22.0
Attachment 5

wedgewood

Notification for Texas Owners/Caregivers

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Quejas: (800) 821-3205 (opción 1)

SOP 5.040
Version 22.0
Attachment 5

Wisconsin law requires the pharmacist to consult with you about any new or changed prescriptions. You may contact the pharmacy about any prescription.

Contact the pharmacy about any delivery concerns including:

- Timeliness of delivery.
- Condition of the prescription drug upon delivery.
- Failure to receive the proper prescription drug product or device

Any prescription which is damaged or lost due to delivery must be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement leads to an interruption in therapy, the dispensing pharmacy must take steps to reduce patient harm.

If a pharmacist fails to consult or resolve your delivery concern, you may contact:

Wisconsin Dept. of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190
(608) 266-2112
dsps@wisconsin.gov
https://dsps.wi.gov (click on File A Complaint)

New Jersey Patient Advisory

Advising patients on the proper disposal of unused prescription drugs and controlled dangerous substances; dispensing prescription drugs.

When unused, unwanted, or expired drugs and medications are not properly, safely, and promptly disposed of:

- there is a risk that the drug or medication can be stolen, diverted, abused, misused, or accidentally ingested, which can pose a risk to the health and safety of the patient and other members of the patient's household;
- children are particularly at risk of accidentally ingesting unused, unwanted, and expired medications that have not been properly, safely, and promptly disposed of;
- when drugs or medications are disposed of in the household trash or flushed down the drain, the drugs and medications can leak into the ecosystem, which can have a potentially adverse or harmful effect on the environment; and
- when drugs or medications are disposed of in the household trash without the drug or medication having been rendered deactivated, inaccessible, or otherwise unusable, the drug or medication may be stolen by individuals seeking to divert, abuse, or misuse the drug or medication.

How to dispose of unused or expired medication:

- Mix medication with an unpalatable substance such as kitty litter or used coffee grounds
- Place the mixture in a disposable container with a lid, or a sealed plastic bag.
- Conceal or remove any personal or drug information on original prescription container before throwing it away in your household trash.
- The sealed container or bag with drug mixture and the empty prescription containers can now be placed in the trash.
- **Do Not** flush unused medication or pour down a sink or drain.
- For more information on disposal of unused medications please contact the pharmacy or visit "How to Dispose of Unused Medicines" https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know

If you have any questions, please contact the pharmacy:
Wedgewood Pharmacy
5301 Young Street, Bakersfield CA 93311
877-734-3338 / 661-377-3333

New Jersey Patient Advisory

Advising patients on the proper disposal of unused prescription drugs and controlled dangerous substances; dispensing prescription drugs.

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If you have any questions, please contact the pharmacy:
Wedgewood Pharmacy
5301 Young Street, Bakersfield CA 93311
877-734-3338 / 661-377-3333

SOP 5.040
Version 22.0
Attachment 7

Connecticut Patient Advisory

wedgewood

If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling 800-842-2649.

wedgewood

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wedgewood

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wedgewood

Notice of Non-Child Resistant Packaging

The medication containers you are receiving may not be child resistant. By signing this form, you indicate that you are requesting a waiver of this requirement and that you agree to have your medication dispensed in "non-child resistant" packaging.

Patient Name _____

Owner/Caregiver Signature _____ Date _____

wedgewood

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Owner/Caregiver Signature _____ Date _____

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Patient Name _____

Owner/Caregiver Signature _____ Date _____

wedgewood

Oregon Prescription Reader Advisory

A prescription reader is a device designed to audibly convey labeling information about your prescription. Please contact us if you would like information about a prescription reader for your pet's prescription.

877-734-3338

wedgewood

Oregon Prescription Reader Advisory

A prescription reader is a device designed to audibly convey labeling information about your prescription. Please contact us if you would like information about a prescription reader for your pet's prescription.

877-734-3338

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Oregon Prescription Reader Advisory

A prescription reader is a device designed to audibly convey labeling information about your prescription. Please contact us if you would like information about a prescription reader for your pet's prescription.

877-734-3338

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Oregon Prescription Reader Advisory

A prescription reader is a device designed to audibly convey labeling information about your prescription. Please contact us if you would like information about a prescription reader for your pet's prescription.

877-734-3338

We're here to help!

Questions? Call our pharmacists at (877) 734.3338:

If the information on the label is not clear to you

If you have any concerns regarding precautions, ingredients or proper storage

If your medication shows signs of deterioration such as change in color, appearance, and/or odor

If your horse or animal is taking additional medicines that may interact with this compounded medicine, and/or has allergies or other medical conditions that should be noted

If your horse or animal experiences any side effects, please call your veterinarian.

wedgewood

Thank you for allowing us to be a part of your animal's care.

This medicine was compounded specifically for your animal to fill a prescription written by your veterinarian. It was specially made to meet your animal's individual needs. For this reason, no standardized information or literature is available with your prescription. If you have not done so, please discuss this medicine with your veterinarian to ensure that you understand (1) why your animal has been prescribed a compounded medicine, (2) how to properly give the medicine, and (3) the interactions, if any, this medicine may have with any other medicines your animal is taking.

Compounding is a long-standing pharmacy practice that allows practitioners to treat their patients' individual needs without being restricted only to off-the-shelf medicines or devices. This medicine was prepared in a compounding pharmacy to meet the specifications ordered by your animal's veterinarian.

Our pharmacists will be happy to help with any additional questions or concerns. If we are unable to resolve your concern, the pharmacy manager shall be notified as soon as reasonably possible and an investigation shall be initiated within 72 hours after being made aware of an incident, accident, variance or unusual occurrence and you will be informed of the outcome by telephone or in writing. If the pharmacy manager is unable to resolve your concern, our accrediting agency ACHC may be contacted at **855-937-2242**.

877.734.3338

precisionpharmacy.com

Report Suspected or Adverse Reactions to the pharmacy and to the FDA using online Form FDA 1932a. This is a compounded drug. Not an FDA approved or indexed drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Not for use in food-producing animals.

WEDGEWOOD PHARMACY LLC	
TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITIES	
SOP NUMBER: 3.030	**VERSION NUMBER: 21.0**
Authorized By:	Date:
Written By: PCCA/Rachel Taggs/Chris Shine	Date: 3-24-2022
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for non-viable and viable environmental monitoring (EM) of the clean room facilities.

2.0 SCOPE

2.1 This procedure applies to Wedgewood Pharmacy, Bakersfield ("Bakersfield") clean room facilities under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>.

2.2 This procedure must be followed to reduce the amount of particulate matter and microbial contamination.

3.0 RESPONSIBILITY

3.1 The Sterile Compounding Pharmacist Supervisor shall supervise this procedure and document that all personnel responsible for EM of the clean room facility comply with this procedure.

4.0 REFERENCE

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 ISO 14644-4 Clean Rooms and Associated Controlled Environments, Part 4

4.3 USP Current Version <1116> "Microbiological Control and Monitoring of Aseptic Process Environments"

4.4 SOP 3.010 Sterile Compounding Area Requirements, or equivalent

4.5 SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent

4.6 SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent

4.7 SOP 4.340 Use, Calibration and Maintenance of the SAS Super 180 Microbiological Air Sampler, or equivalent

4.8 2024 Lawbook for Pharmacy, California; 1751.4 Facility and Equipment Standards for Sterile Compounding

5.0 DEFINITIONS

5.1 CFU – colony forming unit

5.2 TSA – tryptic soy agar

5.3 SDA – sabouraud dextrose agar

5.4 MEA – malt extract agar (may be used when SDA is unavailable)

5.5 PEC – primary engineering control

5.6 Non-viable air sampler – device used to provide quantitative analysis of all airborne particles $\geq 0.5\mu m$ in diameter. (PCCA)

5.7 Viable air sampler – device used to provide quantitative analysis of viable airborne particles. (PCCA)

5.8 Surface contact plate – device of known surface area providing a convex surface to remove viable particles from a flat work surface. (PCCA)

5.9 ISO classifications

5.9.1 ISO Class 5 is equivalent to Class 100.

5.9.2 ISO Class 6 is equivalent to Class 1,000.

5.9.3 ISO Class 7 is equivalent to Class 10,000.

5.9.4 ISO Class 8 is equivalent to Class 100,000.

5.10 Action level – Signals a potential drift from normal operating conditions when normal levels of viable/non-viable particulate in a controlled environment are exceeded; reaching action level requires an investigation and corresponding corrective action (Attachment 4). (PCCA)

5.11 LAFW/BSC – laminar flow workbench / biological safety cabinet

5.12 EM – environmental monitoring

5.13 HEPA – high efficiency particulate air

5.14 IPA – isopropyl alcohol

6.0 FREQUENCY

6.1 Sterile compounding personnel who directly perform sterile compounding duties shall perform glove tests at least every three months when completing a quarterly media fill. The test shall be conducted after garbing and **prior to disinfecting gloves.**

6.2 Surface sampling of all classified areas, and pass-throughs chambers connecting to a classified area, must be completed prior to assigning a BUD longer than the limits established in USP <797> and at least weekly on a regularly scheduled basis regardless of the frequency of compounding. Additionally, surface sampling must be conducted within the PEC at the end of each batch before cleaning and disinfection occurs.

6.3 Viable air samples must be conducted prior to compounding occurs in each classified area (e.g., ISO Class 5 PEC, ISO Class 7 and 8 rooms) under dynamic conditions monthly with use of an impaction air sampler testing a least 1 cubic meter of 1000L of air per location by qualified personnel via media contact plates.

6.4 A sterile compounding pharmacist shall review EM data at least quarterly to ensure no adverse trends exist.

6.5 EM data shall be reviewed, initialed, and dated by the Sterile Compounding Pharmacist Supervisor upon completion.

7.0 EQUIPMENT & SUPPLIES

7.1 Contracted third party (e.g. CTS, C.E.R.T.S, ENV)

7.2 TSA/SDA/MEA media plates. Surface contact plates must contain neutralizers (e.g. lecithin and polysorbate 80).

7.3 Impaction Viable Air Sampler (e.g., SAS Super 180)

7.4 70% sterile isopropyl alcohol

7.5 Appropriate user manuals.

7.6 Sterile compounding garb.

8.0 GENERAL INFORMATION

8.1 EM sampling should flow from "cleanest" areas to "dirtiest" areas.

8.2 Sample sites chosen include locations within ISO class 5, 7 and 8 environments. Sites are also chosen based on greatest risk of contamination (e.g. work areas near the ISO class 5 environment, pass-through boxes, shelving, carts, door handles, etc.).

8.3 Certification and testing of primary and secondary engineering controls shall be performed no less than every six months. Additionally, microbiological air and surface sampling must be performed in the following circumstances: in conjunction with the certification of new facilities or equipment, after servicing of facilities or equipment, in response to identified problems (e.g., positive growth in sterility tests of CSPs), in response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination), and/or in response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents).

8.3.1 Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). The certification shall also include video of smoke studies in all ISO 5 certified areas. (CA 1751.4(f))

8.4 Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CA 1751.4(j))

8.5 Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. (CA 1751.4(j))

8.5.1 Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. (CA 1751.4(j))

8.5.2 Viable air sampling is to be performed under dynamic conditions that simulate actual production. (CA 1751.4(j))

8.5.3 Viable surface sampling is to be performed under dynamic conditions of actual compounding. (CA 1751.4(j))

8.5.4 When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management. (CA 1751.4(j))

Note: In instances where USP and California Board of Pharmacy regulations are in conflict or where current regulations are under board of pharmacy review (e.g., CA BOP reviewing current 2023 compounding regulations in preparation for new USP effective November 1, 2023), Bakersfield will make every effort to follow the strictest rule, regulation, or guideline.

9.0 PROCEDURE

9.1 Upon receipt of commercial media products, verify the manufacturer's certificate of testing and conformance.

9.2 Verify that the certificate of conformance documents the manufacturer's testing of positive and negative controls for the lot of media. If documentation is not provided, quarantine the media and do not use until appropriate certification is received.

9.2.1 Document receipt and verification of the media products on Receipt of Testing Media, Attachment 1, or equivalent, and retain.

9.2.2 Store the media according to the manufacturer's recommendation.

9.3 All sampling should be performed with TSA media incubated at 30°-35°C for no less than 48 hours and then at 20°-25°C for no less than 5 additional days according to USP <797>. Only one TSA sample per sampling location is required if the dual incubation temperature procedure is used.

9.3.1 Alternative incubation schedules using a duplicate TSA media plate per sample location or an alternate media type per sample location may be used as outlined in USP <797> if the procedure outlined in 9.3 cannot be followed.

9.4 Non-viable air sampling

9.4.1 Non-viable air sampling will be performed semi-annually for certification and as needed by a contract vendor for the clean rooms, LAFWs and BSC.

9.4.2 A copy of the final report will be reviewed, initialed and dated by the Sterile Compounding Pharmacist Supervisor and retained.

9.5 Viable air sampling

9.5.1 Viable air sampling will be performed as part of the semi-annual certification of the clean rooms, LAFWs and BSC utilizing the appropriate equipment.

9.5.2 Viable air samples will also be taken monthly with the use of an impaction air sampling device (e.g., SAS 180 Microbiological Air Sampler) by qualified personnel via media contact plates and according to appropriate equipment SOP.

9.5.3 Obtain the appropriate quantity of contact plates from storage.

9.5.4 Label each plate with the following information:

9.5.4.1 Sample code (e.g. A1S25).

9.5.4.2 Date (mmddyy).

9.5.4.3 Initials of the analyst.

9.5.5 Inspect each media plate and discard any damaged or contaminated media and replace. Verify media is within expiration dating.

9.5.6 Don all appropriate clean room garb and sterile gloves as per SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent. Be sure to periodically sanitize gloves with sterile 70% IPA or appropriate disinfectant while sampling.

9.5.7 Record sample location and times samples are taken on Non-Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 5 or Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 7, or equivalent (depending on clean room facility).

9.5.8 Sampling technique

9.5.8.1 Prior to sampling, verify that the battery is charged to last the duration of the sampling period.

9.5.8.2 Wipe the exterior of the unit with a sporicidal agent prior to coming in contact with any controlled environment.

9.5.8.3 Use a new or autoclaved head for the first sampling cycle. The stainless steel sampling head, with its protective plastic lid, may be autoclaved at 121 C for 15 minutes. For each following cycle, the head must be sanitized with 70% sterile IPA. Pre-sterilized plastic sampling heads may also be used.

9.5.8.4 The sampling head can be sanitized by treating the inside and outside surfaces with a wipe saturated with sterile 70% IPA before each cycle.

9.5.8.5 Sanitize the unit using 70% IPA spray for approximately 30 seconds at a distance of approximately 30 cm while the instrument is running. This must be completed before sampling is started and between each sample site.

9.5.8.6 Unscrew and remove the aspirating head by turning counterclockwise.

9.5.8.7 Unscrew the head of the sampler without touching the inside surface or placing your hand over the aspirating section of the head.

9.5.8.8 Insert the contact plate into the plate holder of the sampler and remove the lid of the contact plate.

9.5.8.9 Place the lid face down on a clean wipe that is saturated with 70% IPA.

9.5.8.10 Screw the aspirating head on the sampler and begin sampling, by turning the sampler on.

9.5.8.11 At the end of the sampling cycle, unscrew the aspirating head, put the lid on the plate and remove the contact plate from the sampler.

9.5.9 Clean the unit according to the setting. For example, after sampling the hazardous clean room, clean according to SOP 13.020 Deactivation, Decontamination, Cleaning and Disinfection, or equivalent.

9.5.10 Incubate all samples according to USP. Record daily observation on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent. Samples may be shipped to a contract lab for incubation.

9.5.11 When the environmental monitoring action levels are exceeded, samples will be sent to a third party laboratory to be identified at least to the genus level.

9.5.12 Record viable air sampling results on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent, obtain review by a sterile compounding pharmacist and retain.

9.6 Surface sampling

9.6.1 Surface samples must be performed within the PEC at the end of each batch before cleaning and disinfection occurs. Additionally, surface sampling shall also occur within the classified (ISO Class 5, 7, and 8) areas and pass-throughs prior to assigning a BUD longer than the limits established in USP 797 prior to cleaning on a weekly basis.

9.6.2 Obtain the appropriate quantity of contact plates from storage.

9.6.2.1 Inspect each plate and discard any damaged or contaminated media and replace. Verify media is within expiration dating.

9.6.2.2 Record sample location and times samples are taken on Non-Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 5, or Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 7, or equivalent, depending on clean room facility.

9.6.3 Don all appropriate clean room garb and sterile gloves as per SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent. Be sure to periodically sanitize gloves with sterile 70% IPA or appropriate disinfectant while sampling.

9.6.4 Sampling technique:

9.6.4.1 Aseptically open the media and hold the surface of the agar face down. Do not touch the agar surface. If agar is touched, discard the plate and begin again.

9.6.4.2 Gently touch the media to the desired surface.

9.6.4.3 Replace the cover.

9.6.4.4 Label each plate with the following information, and reference to sampling map, which includes sampling site (Non-Hazardous Clean Room Facility Sampling Map, Attachment 3 or Hazardous Clean Room Facility Map, Attachment 6, or equivalent - depending on clean room facility), and environmental monitoring cover sheet, which includes time, location, and if sample taken was done under dynamic conditions (Non-Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 5 or Hazardous Clean Room Environmental Monitoring Cover Sheet, Attachment 7, or equivelent - depending on clean room facility).

9.6.4.4.1 Sample code (e.g. A1S25).

9.6.4.4.2 Date (mmddyy)

9.6.4.4.3 Initials of the analyst.

9.6.4.5 Clean the sample site per SOP 3.020 Cleaning and Maintenance of the Clean Room Facilities, or equivalent, before proceeding to the next site.

9.6.5 Incubate all samples according to USP. Record daily observation on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent. Samples may be shipped to a contract lab for incubation.

9.6.6 When the environmental monitoring action levels are exceeded, samples will be sent to a third party laboratory to be identified at least to the genus level. Record surface sampling results on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent, obtain review by a sterile compounding pharmacist and retain.

9.7 Personnel monitoring

9.7.1 After initial garbing and glove competency, sterile compounding personnel, involved directly in sterile compounding processes, shall complete the assessment at least once every three months.

9.7.1.1 Personnel who have direct oversight of compounding personnel, but do not compound, must complete a garbing competency evaluation at least every 12 months.

9.7.1.2 Personnel who restock or clean and disinfect the sterile compound areas shall complete the glove and garb evaluation at least semi-annually.

9.7.2 Obtain the appropriate quantity of contact plates from storage.

9.7.2.1 Inspect each plate and discard any damaged or contaminated media and replace.

9.7.2.2 Verify media is within expiration dating and record the appropriate information on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent.

9.7.3 Don all appropriate clean room garb and sterile gloves as per SOP 9.120 Required Garb for Clean Room Facilities Access, or equivalent. Be sure to periodically sanitize gloves with sterile 70% IPA or appropriate disinfectant while sampling.

9.7.4 Sampling technique

9.7.4.1 After sterile garbing is completed and prior **to spraying gloves**, have another staff member aseptically open a media plate. Collect samples from all gloved fingertips and thumbs by rolling fingertip and thumb pad over the agar surface of one hand, making certain not to re-touch areas on agar.

9.7.4.2 Replace the cover.

9.7.4.3 Label the plate with the date, personnel initials, sampler's initials and the hand sampled.

9.7.4.4 Repeat steps 9.7.4.1 – 9.7.4.3 for other hand.

9.7.5 Incubate all samples according to USP. Record daily observation on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent. Samples may be shipped to a contract lab for incubation and/or analysis.

9.7.6 Record personnel monitoring results on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent, obtain review by sterile compounding pharmacist and file all completed documents.

9.8 Action limits

9.8.1 Air sampling (viable)

9.8.1.1 If colonies are present for viable air sampling count and record on EM/Media Fill Daily Monitoring Log, Attachment 2, or equivalent.

9.8.1.2 When the environmental monitoring action levels are exceeded, samples will be sent to a third party laboratory to be identified at least to the genus level. The action limits for air sampling should be derived from USP and historical data. See USP Action Levels for Air, Surface, and Gloves, Attachment 4, or equivalent.

9.8.2 Surface and personnel monitoring

9.8.2.1 The action limits for surface and personnel monitoring should be derived from USP and historical data. See USP Action Levels for Air, Surface, and Gloves, Attachment 4, or equivalent.

9.9 Investigation and corrective actions

9.9.1 If an action level occurs, the Pharmacist-in-Charge and Sterile Compounding Pharmacist Supervisor must be notified and investigation and corrective action should occur with the help of a competent microbiologist. The corrective action

will be dependent on the number of cfu's recovered and the microorganism identified. This may include, but is not limited to, the following actions:

9.9.1.1 Identification of microbial isolates to determine origin.

9.9.1.2 Review of processes and facility improvements.

9.9.1.3 Review of pressure differential information, temperatures and humidity.

9.9.1.4 Review of clean room certification.

9.9.1.5 Review of clean room facility cleaning logs.

9.9.1.6 Review of sterile compounding personnel training records.

9.9.1.7 Additional sanitation.

9.9.1.8 Corrective Action/Preventative Action Plan (CAPA), Attachment 5, or equivalent, from SOP 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management will be completed with an overview and all steps taken to correct the issues. It will also be signed as a final review by the Pharmacist-in-Charge.

9.9.1.9 After the corrective action is taken, the area should be re-sampled within a reasonable time frame. If any sample fails, additional investigation is required.

9.9.2 All action plans will be documented according to SOP 1.030 Deviations – OOS and Corrective and Preventative Action (CAPA) Management, Corrective Action/Preventative Action Plan (CAPA), Attachment 5, or equivalent.

10.0 ATTACHMENTS

10.1 Attachment 1 – Receipt of Testing Media

10.2 Attachment 2 – EM/Media Fill Daily Monitoring Log

10.3 Attachment 3 – Non-Hazardous Clean Room Facility Sampling Map

10.4 Attachment 4 – USP Action Levels for Air, Surface, and Gloves

10.6 Attachment 5 – Non-Hazardous Clean Room Environmental Monitoring Cover Sheet

10.6 Attachment 6 – Hazardous Clean Room Facility Map

10.7 Attachment 7 – Hazardous Clean Room Environmental Monitoring Cover Sheet

11.0 HISTORY

Version Number	Review Date	Effective Date	Description of Change
1.0	10/2009-12/2009	1-1-2010	New SOP
2.0	12-15-2010	1-1-2011	Annual Review; See hard copy for changes
2.0	12-13-2011	1-1-2011	Annual Review; No changes
3.0	1/2013-6/2013	6-14-2013	Annual Review: See hard copy for changes
4.0	6-19-2013	6-19-2013	See hard copy for changes
5.0	7-8-2013	7-9-2013	See hard copy for changes
6.0	2-17-2014	3-11-2014	Annual Review; See hard copy for changes

TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITIES	
SOP NUMBER: 3.030	**VERSION NUMBER: 21.0**
Date Effective:	

Version Number	Review Date	Effective Date	Description of Change
7.0	4-17-2014	5-14-2014	See hard copy for changes
8.0	1/2015-5-2015	6-4-2015	Annual Review; Multiple procedural changes; see hard copy for specifics
9.0	3-9-2016	7-20-2016	Annual Review; Multiple procedural changes; see hard copy for specifics
10.0	8-17-2016	8-19-2016	Updated for TX / NABP law review; specifics for EM review
11.0	9-23-2016	9-29-2016	Updated to add procedure/references for highly pathogenic organisms
12.0	12-2-2016	12-29-2016	Annual Review; Minimal Grammar/Verbiage throughout; Added 8.3; Updated Attachment 5 (Surface Sample Alert Level ISO 7)
13.0	11-30-2017	2-13-2018	Annual Review; Extensive review, updated viable air and surface sampling requirements; See hardcopy for details
14.0	2-18-2019	4-26-2019	Annual Review; Added 5.13; Updated 6.2, 9.4.9.1, 9.4.9.3, 9.4.13, 9.5.1, 9.6.4 and 9.8.3; Updated Attachment 4 and titles of Attachments 3, 7, 8 and 9; Formatting/grammar throughout
15.0	3-13-2020	7-27-2020	Annual Review; Updated 3.1, 6.1, 6.3, 9.4.2, 9.5.2.2, 9.5.7, 9.6.3.4, 9.6.3.6, 9.8.3, 9.8.3.2 – 9.8.3.4, 9.8.4 and Attachments 7 and 9 (new Attachments 6 & 8) ; Added 5.14 – 5.16, 9.4.11, 9.6.3.5; Removed Attachment 6 (referenced CAPA in SOP 1.030, Attachment 1); Grammar/formatting throughout
16.0	3-27-2021	4-27-2021	Annual Review; Updated 4.8, 7.1, 8.3 - 8.5, 9.4.14, 9.8.3.4, 9.8.3.7 and Attachment 3; Grammar/formatting throughout
17.0	3-24-2022	10-5-2022	Annual Review; Updated 4.3, 9.3.1, 9.4.5 – 9.4.7 (removed 9.4.8 and renumbered), 9.5.2.1, 9.5.2.2; Added 9.8.3.5; Grammar/formatting throughout
18.0	9-21-2023	10-10-2023	Annual Review; Updated for new USP 797; See hardcopy and electronic file for specific changes
19.0	12-12-2023	12-19-2023	Updated Attachment 2 to accommodate for two incubation temps
20.0	9-11-2024	9-12-2024	Annual Review; Updated Precision Equine to Wedgewood Pharmacy throughout; Updated 3.1, 6.5, 9.4.2, and 9.9.1; Removed 9.7.4.5 – 9.7.4.10 (garb EM); Added "or equivalent" to Bakersfield SOPs to allow for integration.
21.0	1-7-2025	1-14-2025	Updated language to make clear that samples are sent for genus level identification only when action levels are exceeded. Updated 9.7.4.1 to reflect correct process for glove fingertip and thumb sampling (roll rather than touch plate).

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Receipt of Testing Media

Media Type	Quantity	Manufacturer	Lot Number	Expiration Date	Received By (Initials/Date)
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					
Media: ☐ TSA Other:					

Reviewed By: _____ **Date:** _____

EM/Media Fill Daily Monitoring Log

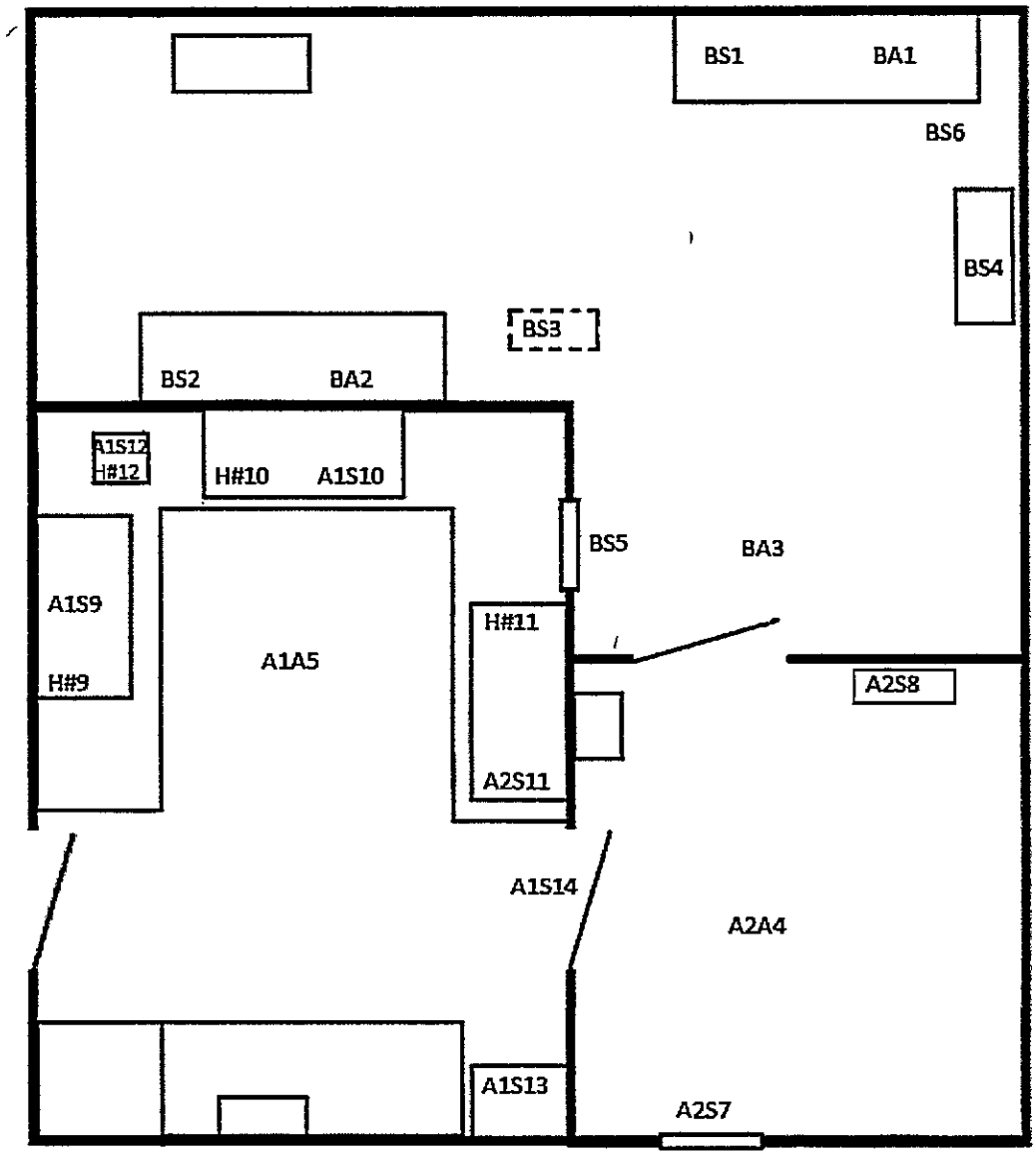
Reason for Sampling:	Media Type:	Media Lot#:

Day #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18		
																				Date	
Incubator #	Data Logger ID:																			Temperature Recordings	
Incubator #	Data Logger ID:																			Temperature Recordings	

Test Type	Sample ID																			Pass	Action	#CFU	Prepared By/ Monitored By	Organism ID

Reviewed By: _____ Date: _____

NON-HAZARDOUS CLEAN ROOM FACILITY SAMPLING MAP



---- = Mobile item

*Items may be added to map by drawing in to scale as best as possible. Items may be removed from map by placing a red "X" over the item.

USP ACTION LEVELS FOR AIR, SURFACE, GLOVES AND GARB MONITORING

Levels for Air Sampling

Classifications	Non-Viable Particles ≥ 0.5µm/ft³ (≥ 0.5µm/m³)	Viable Particles CFU/m³
Critical Areas Class 100 (ISO 5)	100 (3,520)	>1
Non-Critical Areas Class 10,000 (ISO 7)	10,000 (352,000)	>10
Support Areas Class 100,000 (ISO 8)	100,000 (3,520,000)	>100

Levels for Surface Sampling

Classifications	Surface Monitoring (CFU/contact plate)*
Critical Areas Class 100 (ISO 5)	>3
Non-Critical Areas Class 10,000 (ISO 7)	>5
Support Areas Class 100,000	>50

Levels for Gloved Fingertip and Thumb Sampling

Gloved Fingertip and Thumb Sampling	Action Levels (cfu, total from both hands)
After Garbing	>0
After Media Fill Testing	>3

NON-HAZARDOUS CLEAN ROOM ENVIRONMENTAL MONITORING COVER SHEET

Air Samples

Date: _____

BA1- Buffer Room- Inside of hood # 1- _____ @1000 Cubic Liters; Dynamic □
TSA- _____ to _____

BA2- Buffer Room- Inside of hood # 2- _____ @1000 Cubic Liters; Dynamic □
TSA- _____ to _____

BA3- Buffer Room- In front of door @ 1000 Cubic Liters; Dynamic □
TSA- _____ to _____

A2A4- Ante Room 2- Center of room @1000 Cubic Liters; Dynamic □
TSA- _____ to _____

A1A5- Ante Room 1- Center of room @1000 Cubic Liters; Dynamic □
TSA- _____ to _____

Surface Samples

BS1- Buffer Room- Hood #1- DCA- Center of Hood ; Time_____; Dynamic □

BS2- Buffer Room- Hood #2- DCA- Center of Hood ; Time_____; Dynamic □

BS3- Buffer Room- Cart # ___- Handle Center Top; Time_____; Dynamic □

BS4- Buffer Room- Shelf # ___- Second Shelf Down ,Center ;Time_____; Dynamic □

BS5- Buffer Room- Pass through- Bottom, Center ; Time_____; Dynamic □

BS6- Buffer Room - Repeater Pump, Number Pad ; Time_____; Dynamic □

A2S7- Ante Room 2- Pass through- Bottom, Center ;Time_____; Dynamic □

A2S8- Ante Room 2- Garb bench – Center Top ; Time_____; Dynamic □

A1S9- Ante Room 1- Inside of hood #9; Time_____; Dynamic □

A1S10- Ante Room 1- Inside of hood #10; Time_____; Dynamic □

A1S11- Ante Room 1- Inside of hood #11;Time_____; Dynamic □

NON-HAZARDOUS CLEAN ROOM ENVIRONMENTAL MONITORING COVER SHEET

A1S12- Ante Room 1- Inside of hood #12; Time_____; Dynamic □

A1S13- Ante Room 1- Sink- Center near drain ; Time_____; Dynamic □

A1S14- Ante Room 1 – Door handle to garb ; Time_____; Dynamic □

Personnel in clean room while sampling was performed:

_____

_____

_____

_____

_____

_____

Notes/Comments:

_____

_____

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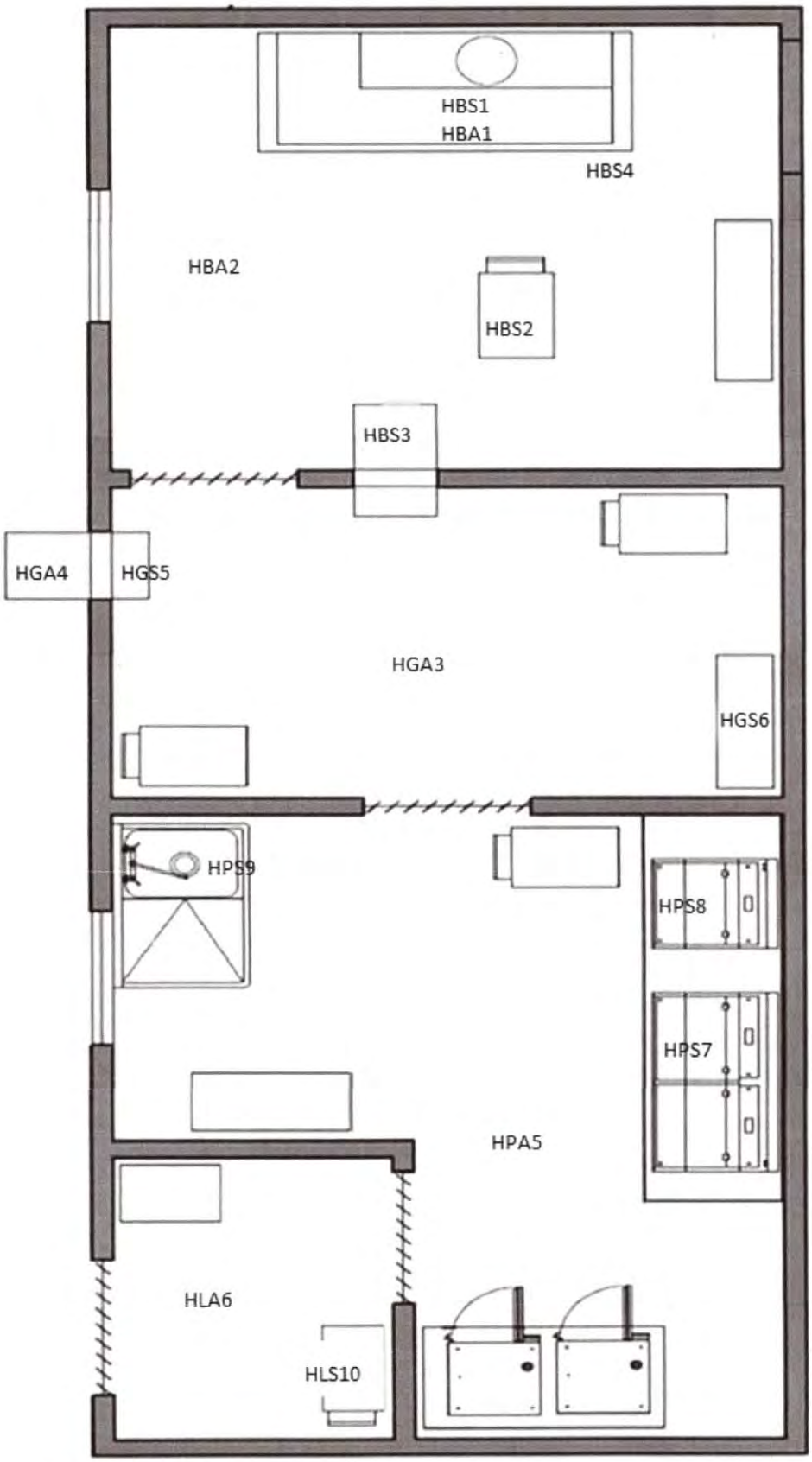
_____

Sampling Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

HAZARDOUS CLEAN ROOM FACILITY MAP



*Items may be added to map by drawing in to scale as best as possible. Items may be removed from map by placing a red "X" over the item.

- - - - = Mobile item

HAZARDOUS CLEAN ROOM ENVIRONMENTAL MONITORING COVER SHEET

Air Samples

Date: _____

HBA1- Buffer Room- Inside of BSC- DCA @1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

HBA2- Buffer Room- In front of door @1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

HGA3- Garbing Room- Center of room @1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

HGA4- Garbing Room- Center of HEPA pass through @ 1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

HPA5- Prep Room- Door to Airlock/Autoclave area @1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

HLA6- Air Lock- Center of room @1000 Cubic Liters; Dynamic □
TSA- _____ to _____
Other: _____

Surface Samples

HBS1- Buffer Room- BSC - DCA- Center of Hood ;Time_____; Dynamic □

HBS2- Buffer Room- Cart #1 – Handle, Center Top ;Time_____; Dynamic □

HBS3- Buffer Room- Pass through- Bottom Center ; Time_____; Dynamic □

HBS4- Buffer Room- Repeater Pump, Number Pad ;Time_____; Dynamic □

HGS5- Garb Room- Pass through – bottom center ; Time_____; Dynamic □

HGS6- Garb Room- Second Shelf Down ,Center ;Time_____; Dynamic □

HPS7- Prep Room- Hood #16- Center Counter ; Time_____; Dynamic □

HAZARDOUS CLEAN ROOM ENVIRONMENTAL MONITORING COVER SHEET

HPS8- Prep Room- Hood #15- Center Counter ; Time_____; Dynamic □

HPS9- Prep Room- Sink – Bottom in front of Drain ; Time_____; Dynamic □

HLS10- Air Lock- Cart # 5- Handle, Center Top ; Time_____; Dynamic □

Personnel in clean room while sampling was performed:

_____

_____

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_____

Notes/Comments:

_____

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_____

_____

Sampling Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

PRECISION EQUINE	
TITLE: SHIPPING OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 5.050	**VERSION NUMBER: 15.0**
Authorized By:	Date:
Written By: Rachel Taggs	Date: 6-21-2021
Reviewed By:	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure that compounded preparations are packaged and shipped to the designated receiver and in a manner such that the product integrity, quality, safety and efficacy are not compromised.

2.0 SCOPE

2.1 This procedure applies to all personnel at Precision Equine (Precision).

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-Charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <800> "Hazardous Drugs – Handling in Healthcare Settings"

4.4 Precision's internal shipping verification temperature studies.

4.5 USP <659> "Packaging and Storage Requirements" (Effective May 1, 2020)

4.6 Current Version Kansas Board of Pharmacy Laws and Regulations; 65-1657. Nonresident pharmacy registration; information required; civil fine; regulatory requirements; drug product selection rules; interstate delivery guidelines; disciplinary action; pharmacies prohibited from advertising unless registered; penalties for violations; injunctive relief; rules and regulations.

5.0 DEFINITIONS

5.1 ISTA – International Safe Transit Association

5.2 Refrigerator – a cold place in which the temperature is maintained between 2° and 8° (36° and 46° F) (USP <659>).

5.3 Controlled room temperature - the temperature maintained thermostatically that encompasses at the usual and customary working environment of 20°-25° (68°-77°F) (USP <659>).

5.4 SDS – safety data sheet

6.0 FREQUENCY

6.1 This procedure shall be followed for each compounded preparation that is to be packaged and shipped.

7.0 EQUIPMENT & SUPPLIES

7.1 Compounded preparation(s) and appropriate equipment/devices, if necessary.

7.2 Appropriate delivery container (e.g. box, insulated cooler, Mylar bag, etc.).

7.3 Appropriate shipping materials (e.g. bubble wrap, packing paper, packing peanuts, ice gel packs, temperature indicators, etc.).

7.4 Detailed delivery instructions, if applicable.

8.0 GENERAL INFORMATION

8.1 Normal delivery time for prescriptions is next day or second day. Geographical locations that will receive the package within two days may be shipped ground. (KS)

8.2 During the months of March through October refrigerated preparations shall be shipped overnight with appropriate packing materials, temperature indicator and shipping container according to ISTA 7E Qualifications. Packages being shipped to a geographical location that will receive the package the next day may be shipped ground.

8.3 If the patient or prescriber needs a preparation before Precision is able to provide it, an offer to transfer the prescription to a pharmacy of their choice may be made. (KS)

8.4 Hazardous drugs must be transported in containers that minimize the risk of breakage or leakage (e.g. secondary internal packaging).

8.5 Hazardous drugs shall be transported in a format that is consistent with the carrier's policies.

8.6 When shipping hazardous drugs, Precision will consult the transport information on the SDS.

9.0 PROCEDURE

9.1 General shipping procedures.

9.1.1 A pharmacist on duty shall ensure that compounded preparations are properly packaged and shipped without compromising the product integrity, quality, safety and efficacy.

9.1.2 All compounded preparations shall be packaged and shipped in appropriate containers that will protect the preparation from wide variations in temperatures, structural damage, or light.

9.1.3 Applicable packages will be shipped with an activated temperature indicator appropriate to the preparation(s) recommended storage temperature.

9.1.4 Deliveries of all medications, dispensed or distributed, are sent via a common carrier utilizing a secure and traceable method.

9.1.5 A packing slip and/or receipt should be provided for each preparation along with devices or equipment that may be included with each product.

9.1.5.1 The location of the delivery shall be recorded on the delivery tag.

9.1.5.2 Delivery tags shall be kept as the internal shipping record in the pharmacy for the period required by state and federal regulations. Shipping records may also be obtained through third party shipping company upon request.

9.1.5.3 Staff responsible for packing and shipping shall ensure all delivery tags are retained and turned over to accounting in a timely manner.

9.1.5.4 The authorized recipient signature shall be recorded by delivering agency when requested by receiver or Precision.

9.1.5.4.1 Exception to 9.1.5.4: All controlled substance prescriptions will require signature upon delivery.

9.1.6 A safety data sheet (SDS) for each ingredient used in the compounded preparation shall be available at the pharmacy in case a spill or accident occurs while delivering the preparation.

9.1.7 If special instructions are required for proper inspection of the preparation, they will be transmitted to the designated receiver prior to delivery of the package or included in the package.

9.1.8 Storage instructions shall be provided to the designated receiver via the prescription label to ensure that the preparation is stored appropriately at the patient's home or at the health care facility.

9.1.9 If applicable, specific handling instructions shall be included on the exteriors of shipping containers packed with compounded preparations (e.g. Refrigerate Upon Arrival).

9.1.9.1 When shipping hazardous drugs internal packaging shall be labeled as such.

9.1.10 All packages shall include a Precision Equine Information Sheet (SOP 5.040 Counseling of Compounded Preparations, Attachment 1) which includes and may not be limited to:

9.1.10.1 Instructions on how to contact the pharmacy for a consultation with a pharmacist via a toll-free number.

9.1.10.2 Information regarding storage and stability.

9.1.10.3 Information regarding proper disposal of medications.

9.1.10.4 Information regarding Precision Equine's Privacy Notice.

9.1.10.5 Information regarding shipment temperature indicators.

9.1.11 Prescriptions received for an acute illness shall be priority for processing and patients shall have options for expedited delivery. Expedited delivery options may include overnight early morning delivery or Saturday delivery when possible. (KS)

9.2 Refrigerated shipments.

9.2.1 All items in 9.1 shall be followed including items outlined in this section.

9.2.2 During the months of March through October all refrigerated preparations will be shipped overnight. This time frame may vary based on information received from the third party shipping company and current temperatures.

9.2.3 All preparations requiring refrigeration (Attachment 4) shall be packaged according to ISTA 7E Qualification recommendations (Attachments 1, 2 and 3) and include the appropriate temperature indicator strip.

9.2.3.1 Each package will include Precision Equine Information Sheet (Attachment 1, SOP 5.040 Counseling of Compounded Preparations)

detailing instructions to follow if the indicator strip is out of the specified range.

9.3 Controlled room temperature shipments.

9.3.1 All applicable items in 9.1 shall be followed including items outlined in this section.

9.3.1.1 Each package will include Precision Equine Information Sheet (Attachment 1, SOP 5.040 Counseling of Compounded Preparations) detailing instructions to follow if the indicator strip is out of the specified range.

9.4 Transit incidents.

9.4.1 Shipping exceptions.

9.4.1.1 Precision will be notified by the third party shipping company via email once a delivery exception has occurred. Every attempt will be made to contact the patient and/or prescriber via phone and/or email to advise them of the situation. If the preparation will not reach the end user in the appropriate time frame or if the patient/prescriber is out of medication, Precision will offer to send a replacement or offer to transfer the prescription to a pharmacy of their choice. (KS)

9.4.1.2 If a replacement is sent, the original package should be returned to the pharmacy.

9.4.2 Damaged preparation.

9.4.2.1 In the event the preparation is damaged in transit, Precision will send replacement item(s) and request the original package is returned to sender, if possible.

9.4.3 Temperature excursions.

9.4.3.1 In the event Precision is notified that a preparation was received out of the specified temperature range, Precision will send a replacement and issue a pick up for the temperature-sensitive preparation to be destroyed at the pharmacy according to SOP 9.090 Proper Disposal of Pharmacy Waste.

9.4.3.2 Temperatures are considered out of range when Warm Mark temperature indicators:

9.4.3.3.1 Controlled room temperature: a package that has entered the "prolonged" range for any period of time (any color change) shall be returned.

9.4.3.2.2 Refrigerated: a package that has entered the "moderate" range for any period of time (any color change) shall be returned.

9.4.4 In each case a pharmacist on duty shall be responsible for decisions and complete any necessary documentation (e.g. OOS, incident report, etc.).

10.0 ATTACHMENTS

10.1 Attachment 1 - ISTA 7E Qualified Large Cooler Pack Out

10.2 Attachment 2- ISTA 7E Qualified Medium Cooler Pack Out

10.3 Attachment 3 - ISTA 7E Qualified Small Cooler Pack Out

10.4 Attachment 4 – Refrigerated Preparations at Precision Equine

11.0 HISTORY

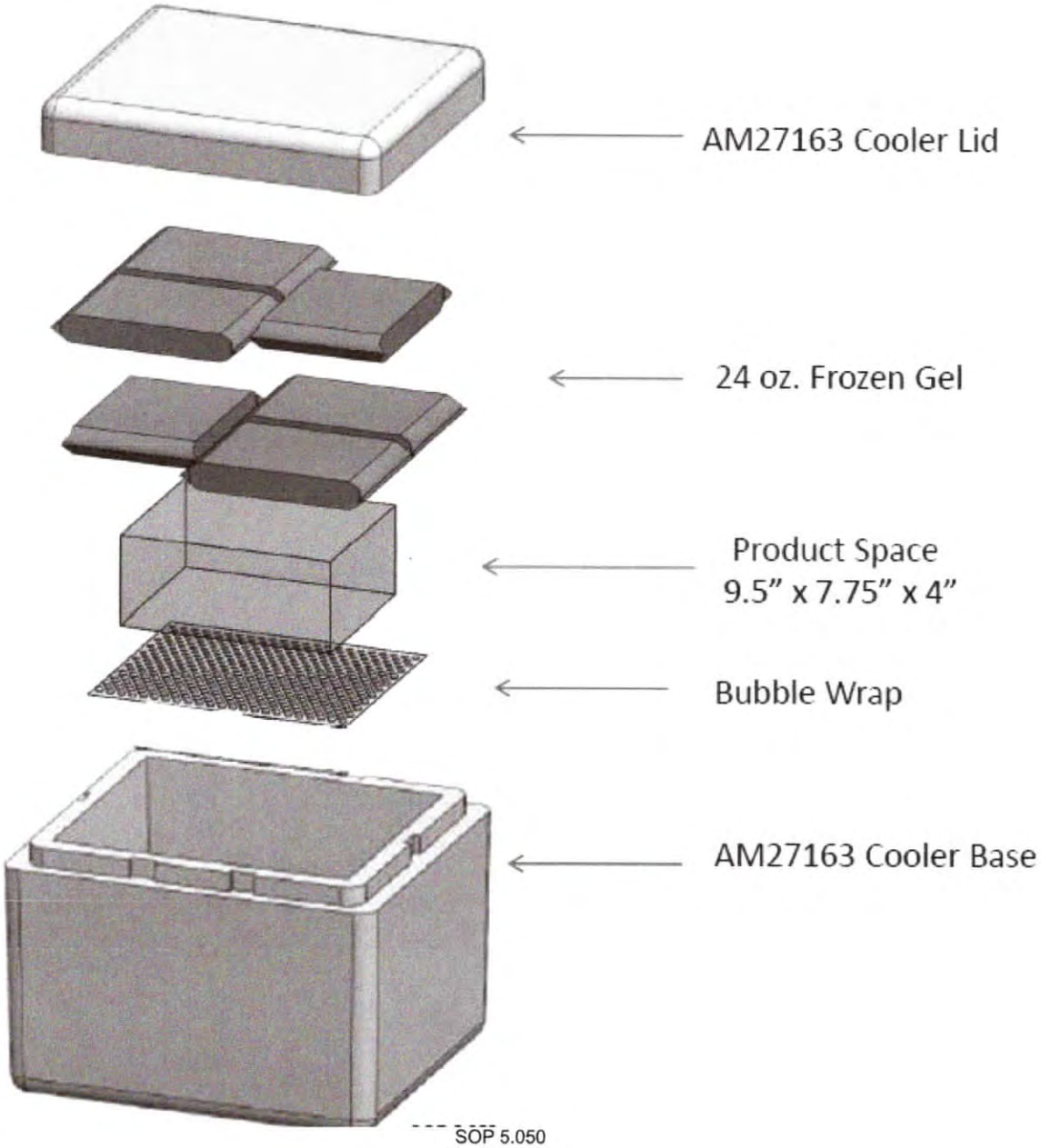
Version Number	Review Date	Effective Date	Description of Change
1.0	10-2009-12/2009	12-14-2009	New SOP
2.0	11-12-2010	1-1-2011	See hardcopy
2.0	12-20-2011	1-1-2011	Annual Review; No Changes
3.0	2-13-2013	6-14-2013	Annual Review; See hardcopy
4.0	12-30-2013	12-30-2013	See hardcopy
5.0	2-18-2014	2-18-2014	See hardcopy
6.0	3-27-2014	3-27-2014	See hardcopy
7.0	10-29-2014	11-11-2014	Added exemption to CS signature required 9.4.2.1
8.0	3-27-2015	4-1-2015	Annual Review; Added 9.11
9.0	6-22-2016	6-30-2016	Annual Review; Updated to include temperature indicators
10.0	5-11-2017	5-15-2017	Annual Review; Updated Attachment 4 (added Rifampin Suspension)
11.0	3-26-2018	12-4-2018	Annual Review; Added 9.3.1.2 and 9.3.3.2; Updated Attachment 4; Grammar throughout
12.0	11-26-2019	12-17-2019	Annual Review/Updated for USP <800>; Added 4.3, 5.4, 8.4-8.6, 9.0.8.1; Updated 9.0.1 and Attachment 4
13.0	8-6-2020	9-10-2020	Annual Review; Added 4.6 (and included references throughout) and 9.1.10; Reformatted numbering to Section 9.0; Updated 9.1.2, 9.1.4.4.1, 9.2.2 and Attachment 4; Removed references to UPS and replaced with references to third party shipping company
14.0	6-21-2021	12-27-2021	Annual Review; Updated 9.4, 9.4.3.1 and 9.4.3.2; Grammar/formatting throughout
15.0	9-20-2022	11-29-2022	Updated Precision Pharmacy to Precision Equine (Precision) throughout; Updated temperature indicator requirements; Grammar/formatting

The remainder of this page intentionally left blank.

Attentus Large Cooler Pack Out

ISTA 7E Qualified

Summer Pack Out Diagram

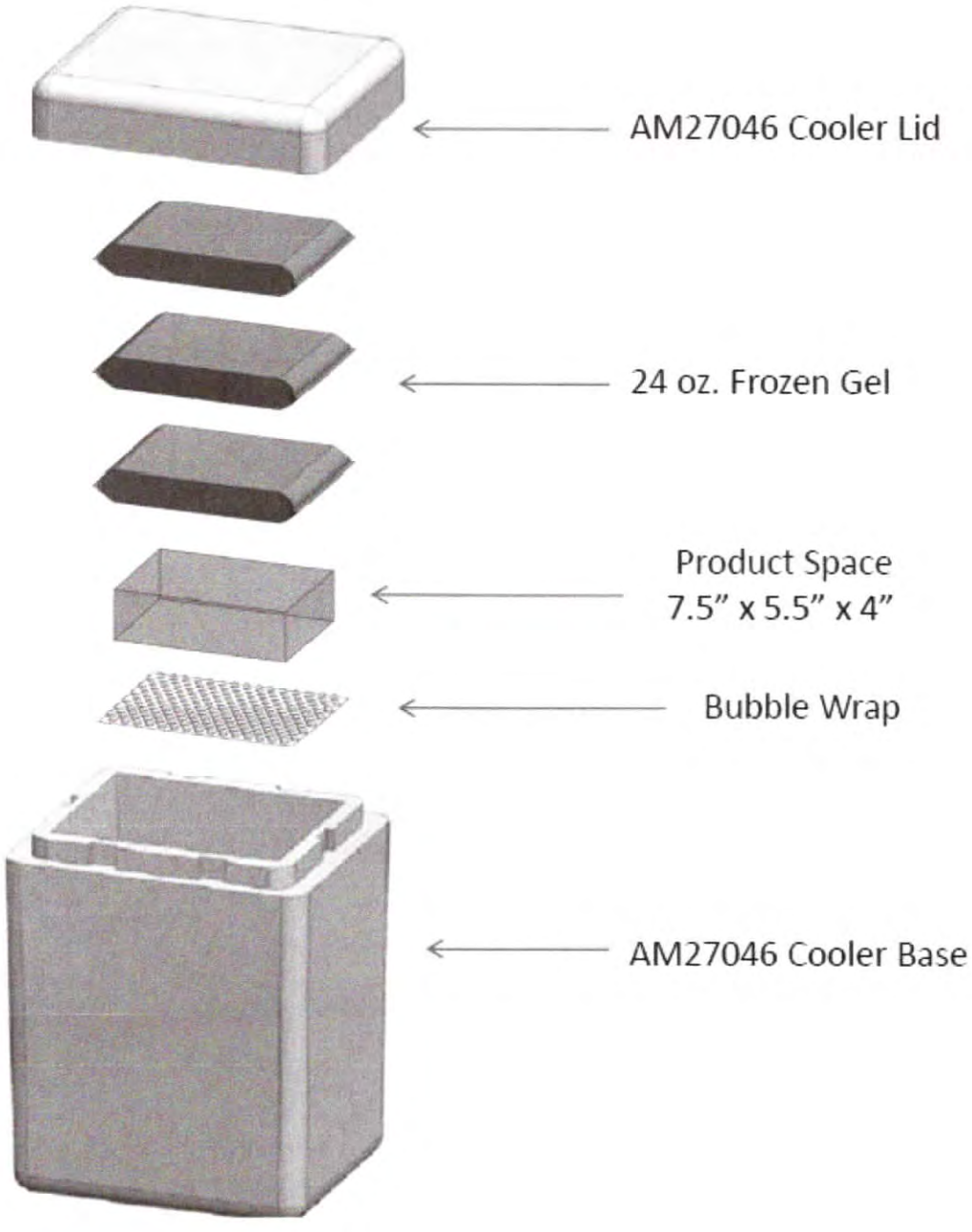


SOP 5.050
Version 15.0
Attachment 1

Attentus Medium Cooler Pack Out

ISTA 7E Qualified

Summer Pack Out Diagram

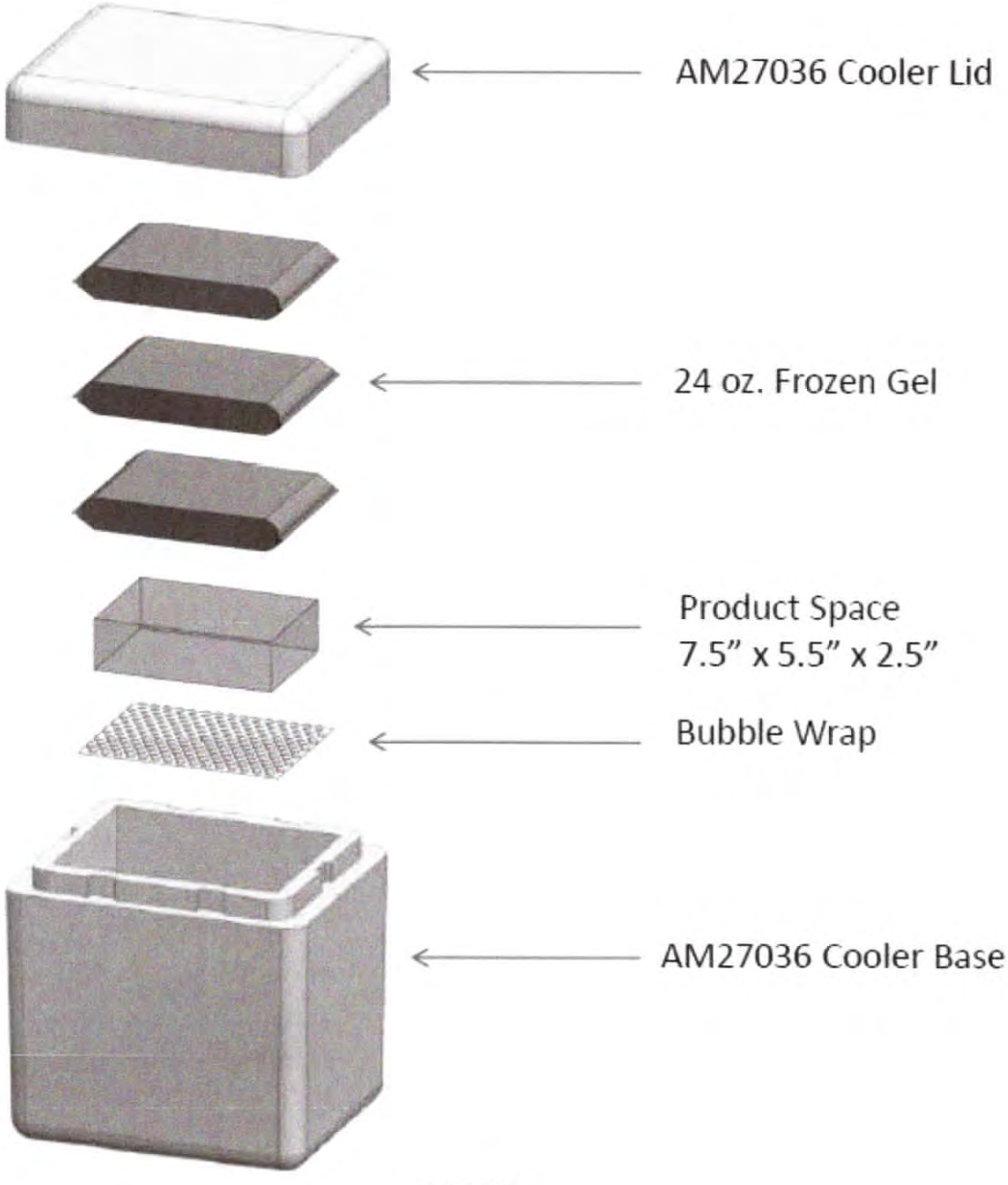


SOP 5.050
Version 15.0
Attachment 2

Attentus Small Cooler Pack Out

ISTA 7E Qualified

Summer Pack Out Diagram



SOP 5.050
Version 15.0
Attachment 3

Refrigerated Preparations at Precision Pharmacy

Subject to change at any time without notice.

AZITHROMYCIN/RIFAMPIN 100MG/100MG/ML SUSPENSION
CISAPRIDE ORAL 50MG/ML SUSPENSION
CLARITHROMYCIN/RIFAMPIN 75MG/50MG/ML SUSPENSION
CLOTRIMAZOLE (UTERINE SUSPENSION) (PF) (NON-STERILE) 2% SUSPENSION
DESLORELIN IN WATER FOR INJ. IMMEDIATE RELEASE 50MCG/ML INJECTABLE
DESLORELIN (AS ACETATE) IR 1.5MG/ML INJECTABLE
FLUCONAZOLE (UTERINE SUSPENSION) (PF) 100MG/50ML SUSPENSION
HISTRELIN (AS HISTRELIN ACETATE) 0.5MG/ML INJECTABLE
HISTRELIN (AS HISTRELIN ACETATE) 1MG/ML INJECTABLE
MICONAZOLE (UTERINE SUSPENSION) (PF) 4MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED) 100MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED) 150MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED) 2.2GM/15ML SUSPENSION
OMEPRAZOLE (BUFFERED) 2.2GM/30ML SUSPENSION
OMEPRAZOLE (BUFFERED) 200MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED) 220MG/ML (2.2GM/10ML) SUSPENSION
OMEPRAZOLE (BUFFERED) 2GM/30ML SUSPENSION
OMEPRAZOLE (BUFFERED)(FC) 100MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED)(FC) 2.2GM/15ML SUSPENSION
OMEPRAZOLE (BUFFERED)(FC) 20MG/ML SUSPENSION
OMEPRAZOLE (BUFFERED)(FC) 220MG/ML (2.2GM/10ML) SUSPENSION
OMEPRAZOLE (BUFFERED)(FC) 6MG/ML SUSPENSION
OMEPRAZOLE/FAMOTIDINE (BUFFERED) 2.2GM/1GM/15ML SUSPENSION
OMEPRAZOLE/SUCRALFATE 2GM/2GM/15 ML PASTE
PERGOLIDE (SUGAR FREE) 1MG/ML SUSPENSION
PERGOLIDE APPLE FLAVORED 0.3MG/ML SUSPENSION
PERGOLIDE APPLE FLAVORED 0.5MG/ML (1MG/2ML) SUSPENSION
PERGOLIDE APPLE FLAVORED 1.25MG/ML SUSPENSION
PERGOLIDE APPLE FLAVORED 1.5MG/ML SUSPENSION
PERGOLIDE APPLE FLAVORED 2MG/ML SUSPENSION
PERGOLIDE APPLE FLAVORED** 1MG/ML SUSPENSION
PERGOLIDE MAPLE FLAVORED 0.5MG/ML (1MG/2ML) SUSPENSION
PERGOLIDE MAPLE FLAVORED 1.5MG/ML SUSPENSION
PERGOLIDE MAPLE FLAVORED 1MG/ML SUSPENSION
PERGOLIDE MAPLE FLAVORED 2MG/ML SUSPENSION
PERGOLIDE PEPPERMINT FLAVORED 1MG/ML SUSPENSION
PERGOLIDE VANILLA FLAVORED 1MG/ML SUSPENSION
PERGOLIDE/CYPROHEPTADINE HCL 1MG/100MG/ML SUSPENSION
PERGOLIDE/CYPROHEPTADINE HCL 1MG/200MG/5ML SUSPENSION
PERGOLIDE/CYPROHEPTADINE HCL (FC) 1MG/100MG/ML SUSPENSION
PREDNISOLONE ORAL 100MG/ML SUSPENSION
PREDNISOLONE ORAL 10MG/ML SUSPENSION
PREDNISOLONE ORAL 20MG/ML SUSPENSION
SULFADIAZINE/PYRIMETHAMINE/FOLIC ACID 33.3%/1.67%/0.13% SUSPENSION
THROAT SPRAY (DEXAMETH/DMSO/NITRO/GLYCERIN) IN WATER 0.04%/22.2%/0.007%/22.2% SOLUTION
URSODIOL 100MG/ML SUSPENSION
URSODIOL 50MG/ML SUSPENSION

wedgewood
PHARMACY

RECEIVED
11/21/24

November 20, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521

RE: Wedgewood Pharmacy LLC - New Application

Dear Sir/Madam:

Enclosed please find an application for Wedgewood Pharmacy LLC, previously known as Precision Pharmacy. Wedgewood Pharmacy LLC is a compounding pharmacy located in Bakersfield, California that compounds both non-sterile and sterile medications for veterinary use.

Wedgewood Pharmacy LLC, formerly known as Precision Pharmacy, once held license number PH02584. Sadly, our designated Nevada pharmacist passed away, and due to staffing shortages, we were unable to find a replacement. Consequently, we halted shipments to Nevada. Today, we are pleased to announce that Ragini Shah, a licensed Nevada pharmacist, has joined our team. Please accept the enclosed pharmacy application for licensure.

Should you have any questions or require additional information, please do not hesitate to contact me at (207) 518-0124 or nasro.ali@wedgwood.com.

Sincerely,

Nasro Ali
Licensing Coordinator

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

[redacted]

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V

Section 1: Personal Information

First: HARSHA Middle: GHATGE Last: NAGARAJA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 21552 Specialty: Neurology

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): ELKO Spine & Rehabilitation Institute

Practice Address: 2219 5th street Suite #:

City: ELKO State: NV Zip: 89801

Telephone: 7757779669 Fax: Email: [redacted]

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

PMP

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✓	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

please see separate attached statement for details

[redacted]

Original Signature (electronic, copies or ~~stamps~~ not accepted)

1/28/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HARSHA, NAGARAJA
Print Name (First, Last)

2/3/2025
Date

[redacted]
Original Signature (electronic copies or ~~stamps~~ not accepted)

2/3/2025
Date

Board Use Only: Date Processed: 2/13/25 Amount: $200.00

1/28/2025

To whom it may concern,

I was involved in a car accident on January 21, 2024 and there was a suspicion of substance use at the time. I had 2-3 drinks earlier that day and was given an option to give a voluntary breath sample while in the hospital due to my injuries and refused. Due to this I was referred to the NCMB for further evaluation, and in April 2024 I was recommended to have inpatient treatment (10 weeks total with a discharge date of 6/15/24 at Pavillon). My medical license was not suspended; however, I did enter into a temporary nonpractice agreement with the state of North Carolina's medical board at the time.

I do not have any outstanding legal charges from this event and was not charged with a substance abuse related ticket. Additionally, all moving violations from the incident have since been vacated.

My current license is unrestricted. I am currently under a 5-year monitoring contract with the NCPHP (signed 6/17/24). I continue currently following NCPHP recommendations which include 4 AA meetings weekly, an AA sponsor meeting once monthly, a workplace supervisor meeting once monthly, a substance abuse counselor meeting monthly (discharged as of December 2024), a monthly meeting with NCPHP representative, and random urine drug screens 3-4 times a month.

The Nevada Board of medicine is aware of the above information. My contact at NVPHP is Dr. [redacted]

Thank you for your time and attention,

[redacted]

Harsha Nagaraja, MD

North Carolina Professionals Health Program (NCPHP)
Recovery Monitoring Contract

Name: **Harsha Ghatge Nagaraja MD**

Address: [redacted]

This Recovery Monitoring contract ("contract") specifies the terms under which NCPHP will act in a monitoring and support role to my professional licensing board and equivalent state licensing boards, hospitals, employers, medical societies, legal entities, the Drug Enforcement Agency, and others. This contract remains in effect until such time as it is completed or both parties mutually agree to end the contract.

_____ **1.** I understand that I have been diagnosed with **Alcohol Use Disorder, Moderate** and my recovery from that condition will be monitored by NCPHP.

_____ **2.** I agree to engage in respectful and courteous communication with NCPHP staff at all times. I understand that threatening, vulgar, or disrespectful language or behavior can result in my exclusion from NCPHP, loss of support, and potential legal action by NCPHP, if warranted. I can expect to be treated with equal respect and courteous behavior by NCPHP staff. Should I experience anything other than such, I will report it to NCPHP leadership for prompt action.

_____ **3.** I understand that all evaluation, treatment, therapeutic intervention, or education services will be obtained at my own expense. I understand that NCPHP does not provide treatment services.

_____ **4.** I agree to the following monitoring plan:

- **To abstain from alcohol, cannabis (e.g., CBD and Delta-8 products) and all mood-altering substances unless prescribed by my primary care physician or psychiatrist and approved by NCPHP.**
- **To follow all recommendations from Pavillon.**
- **To engage in individual psychotherapy with an NCPHP-approved therapist at a frequency and duration determined by the provider.**
- **To attend 90 abstinence-based self-help groups in 90 days following discharge as recommended by Pavillon.**
- **After completing 90 in 90, I agree to attend 4 abstinence-based self-help meetings per week in year one and 3 per week thereafter. NCPHP strongly encourages participation in a minimum of 2 Caduceus meetings per month. I agree to record my meeting attendance through a mobile app made available to me by NCPHP and the NCPHP Random Toxicology Screening Program.**
- **To not return to the practice of medicine before 7/1/24 and until cleared to do so by NCMB, NCPHP and my providers.**
- **To return to Pavillon for Relapse Prevention Week on March 23, 2025.**

_____ **5.** I agree to attend abstinence-based self-help meetings. These meetings can include 12-step meetings, Dharma Recovery, Celebrate Recovery, Smart Recovery, or other abstinence-based groups.

_____ **6.** I agree to enroll in the NCPHP Random Toxicology Screening Program by the Third-Party Administrator (TPA) designated by NCPHP. By my enrollment I agree to abide by the rules and provisions of this program, including providing a sample when selected to do so within the parameters set by the TPA and NCPHP. I also understand that by enrolling in this program, I agree to the release of the results of my screens to NCPHP by the TPA and allow communication between NCPHP and the TPA to facilitate this process.

_____ **7.** I understand that dilute or other specimen results of concern may be retested. I understand that I will be billed for the additional charges for retesting.

_____ **8.** I agree to pay for random toxicology testing by NCPHP or its vendors. Failure to pay for screens may be considered a violation of my contract.

_____ **9.** I agree to contact NCPHP within 24 hours of any unintentional or intentional use of alcohol or other mood-altering substance(s) not previously made known to NCPHP. Failure to do so will be considered a breach of this contract and may result in loss of anonymity (if applicable) and subsequent report to my professional licensing board, employer, or other entities to which NCPHP previously supported me.

_____ **10.** I agree to random visits by NCPHP Field Coordinator, **Jason Yates CCS, LCAS, LCSW**, which may include weekend visits (Saturday/Sunday). I will notify my Field Coordinator in advance of any travel that may interfere with Field Coordinator visits.

_____ **11.** Field Coordinator visits are partly for the purpose of obtaining random toxicology screens to document abstinence, which includes the possible collection of urine, saliva, hair, nail clippings, blood, or other biological samples for testing. Therefore, I agree to promptly communicate with a Field Coordinator and remain available for random visits. I will immediately notify a Field Coordinator of travel outside of my usual work and home geographic areas. I realize that refusal or inability to meet (other than an emergency) with a Field Coordinator may be considered an issue of non-compliance and must be reported to the NCPHP Compliance Committee as a violation of my contract. The Compliance Committee is the independent body that oversees the work done by NCPHP.

_____ **12.** I understand that any ingestion of ethyl alcohol (including mouthwash, "non-alcoholic" beer, OTC cough syrup) or ingestion of some other substances such as poppy seeds may cause a positive drug screen that cannot be differentiated from intentional ingestion. If this situation occurs, NCPHP may require a comprehensive evaluation at an NCPHP-approved facility or additional testing via other means.

_____ **13.** NCPHP discourages travel during the first year of monitoring. For any travel while under monitoring, I agree to the following:

- Discuss non-emergency travel plans with my Field Coordinator at least 2 weeks in advance of travel.
- Inform my Field Coordinator of any emergency travel within 24 hours.
- For all travel, email, or other written notification to my Field Coordinator and NCPHP office is required.

_____ **14.** For travel while participating in daily check-ins for random toxicology screening, I agree to the following:

- Check in each weekday to the toxicology screening program while traveling, just as at home.
- Contact TPA at least 5 business days in advance of travel to determine available testing sites at my destination.
- Take chain-of-custody (COC) forms or any testing materials with me. I understand that not having a COC form or testing materials with me is not a reason to miss a screen.
- A missed screen is a violation of my contract and may be reported to the NCPHP Compliance Committee.
- Travel to locations outside the US or other locations where a screening site is not available must be discussed with and approved by my Field Coordinator 4 weeks in advance. I understand that I will be required to submit to specific testing upon my return.
- For emergency situations where I may be unable to screen if selected, I will notify my Field Coordinator as soon as possible, preferably within 24 hours.

_____ **15.** If I need prescribed medication for an acute medical condition, I agree to:

- Obtain approval from NCPHP prior to the use of any medication (including over the counter medications) unless used during an emergency. In the case of such emergency, I agree to notify NCPHP of the use of such medication within one business day.
- Communicate with my Field Coordinator or Director regarding use of any potentially addictive or impairing medications, prescription or otherwise, prior to actually starting the medication.
- Send NCPHP by secure text, e-mail, or other electronic communication a picture(s) of the prescription bottle within 24 hours of the time such prescription is picked up from the pharmacy or dispensing entity, prior to actually starting the medication.
- In the case of emergency surgery, inform Field Coordinator as soon as possible of the surgery and what mood-altering or potentially addictive medications were required prior, during or after surgery.
- I understand that the use of a potentially addictive or controlled substance medication for an acute medical condition requires that I refrain from all medical practice until at least twenty-four (24) hours after the last dose of the medication or as outlined in my individualized monitoring contract with NCPHP. I understand that NCPHP will obtain urine and/or other screens from me as I am returning to practice.
- I will make virtual or face-to-face contact with my NCPHP Director prior to beginning work to verify that I have discontinued all use of any potentially addictive or impairing medication.
- I will provide the name and contact information of my prescribing provider and primary care physician/PA/NP and any changes to this information to NCPHP office. Participant shall also provide to NCPHP a signed release of information allowing communication between NCPHP and prescribing provider, primary care physician/PA/NP, and pharmacist as appropriate.
- I will have someone else (e.g., spouse, partner, significant support person, other family member, etc.) maintain possession of any potentially addictive or impairing medication(s). I will inform Field Coordinator as to who will hold potentially addictive or impairing medication for me.
- Report any dosage or other changes in the use of such potentially addictive or impairing medication, both prescribed and over-the- counter, to Field Coordinator prior to such changes.
- Inform Field Coordinator of any planned elective surgery or procedure and provide a list of any anticipated potentially addictive or impairing medication(s) prior to such surgery or procedure.

Note: While a participant in NCPHP, the use of non-NCPHP-approved potentially addictive or impairing medications, prescription or otherwise, may be considered a relapse and could result in a report of such use to the Compliance Committee of NCPHP. The Compliance Committee may require additions or

changes to your individual monitoring contract and also has the authority to require anonymity breaks to your regulatory or licensing board.

_____ **16.** I agree to follow all federal, state, and my professional licensing board rules, regulations, and position statements, and the American Medical Association Code of Medical Ethics (if applicable) regarding the prescribing or provision of any medications to anyone to whom I provide medical care, including myself.

_____ **17.** If I have been recommended to see a therapist and/or psychiatrist by NCPHP or a treatment provider, I agree to have an appointment to establish care with a therapist and/or psychiatrist after signing this contract. My therapist and/or psychiatrist will submit quarterly reports to NCPHP. It is my responsibility to ensure these reports are submitted by the deadline given. I hereby authorize my therapist and/or psychiatrist to release and receive information from NCPHP for the duration of this contract.

My therapist is:

Name _____
Address _____
_____
Phone _____
Email _____

My psychiatrist is: N/A

Name _____
Address _____
_____
Phone _____
Email _____

_____ **18.** I agree to have an appointment to establish care with the above provider(s) no later than two weeks from the start date of this contract.

_____ **19.** I agree to meet with my workplace advocate at least monthly. My advocate will submit quarterly reports to NCPHP. It is my responsibility to ensure these reports are submitted by the deadline given. My advocate must have frequent (at least weekly) contact with me, should be in the same field, should be sensitive to confidential information, and cannot be a subordinate or employed by me, unless approved by NCPHP. I hereby authorize my advocate to release and receive information from NCPHP for the duration of this contract. My workplace advocate is:

Name _____
Address _____
_____
Phone _____
Email _____

_____ **20.** I understand that if I have significant disagreement with NCPHP findings or recommendations, I may report my situation to the Review Committee (RC) of NCPHP. In regards to this process, I agree to first notify NCPHP of my disagreement with my diagnosis, need for additional assessment, need for treatment, or need for monitoring by NCPHP. I agree to first meet with NCPHP staff to discuss my disagreement prior to requesting a meeting of the RC. If unable to resolve my disagreement at the NCPHP staff level, I may proceed to review by the RC.

_____ **21.** If I enroll as an anonymous participant, I can anticipate remaining in that status unless NCPHP determines that it is legally required to report me to my professional licensing board, which generally would occur if one of the following occurs:

a. I constitute an imminent danger to patient care by reason of mental illness, physical illness, substance use disorder, professional sexual misconduct, or any other reason.
b. I refuse to submit to an assessment as ordered by my professional licensing board or enter into a contract and fail to comply with the terms of that contract, am still impaired or unsafe to practice after treatment, or display professional incompetence.
c. It reasonably appears that there are other grounds for disciplinary action (for Pharmacy & Veterinarian licensees only).

_____ **22.** I understand that I may be asked to travel to the NCPHP office to meet with NCPHP staff. I agree to schedule meetings in a timely manner.

_____ **23.** I understand that I may be asked to participate in an exit survey for the purpose of providing feedback to NCPHP about my treatment (if applicable) and monitoring experiences.

_____ **24.** I will notify NCPHP of any change in address, phone numbers, or employment, malpractice suits, arrests, psychiatric or medical hospitalizations or any other significant events.

_____ **25.** I understand that NCPHP does not provide medical or other health care services or any licensed professional services on my behalf. I understand that it is my responsibility to obtain qualified medical treatment and that NCPHP assumes no responsibility in this regard. In consideration for the opportunity to participate with NCPHP, I agree to release and discharge NCPHP and the trustees, officers, agents and employees of NCPHP from any claims, demands, obligations, costs incurred, expenses (including court costs and reasonable attorneys' fees), damages or causes of actions of any nature whatsoever arising out of, or related to, or in any way connected with, any disclosure, release, act or omission in connection with my participation with NCPHP and acknowledge receipt of a copy of this contract.

_____ **26.** I understand that NCPHP may encourage my spouse, partner, and/or children to be seen by a family counselor and to participate in a family program, self-help group or private counseling, if and when appropriate.

_____ **27.** If I have been referred to NCPHP by my professional licensing board or if NCPHP deems my anonymity should be broken, then I authorize NCPHP to disclose any information it may have concerning me including, but not limited to, my involvement with NCPHP, my illness, diagnosis, prognosis, treatment, or any other information, to my professional licensing board, its members, employees, or agents for its use in the discharge of its duties while enforcing the laws my licensing board is responsible to uphold. If not previously revoked, this consent will terminate upon the successful completion of this contract. NCPHP is acting in reliance on the consent to disclosure when the contract is

signed. In the above circumstances, I also authorize NCPHP to disclose information and records protected by 42CFR Part 2 to my professional licensing board and have signed a separate Consent form (Consent A).

_____ **28.** If I move to or begin practice in another state before completing this contract, I will contact the Professionals Health Program (PHP) in that state and my monitoring may be transferred to that state, if appropriate. If I fail to contact the PHP in that state, I authorize NCPHP to notify the other state PHP of my participation with NCPHP.

_____ **29.** This Stage I contract will run for **3 Years.** I understand that I will be charged a monitoring fee of **$110** per month. This contract will begin **6/17/2024 or upon receipt of signed document** and end **6/17/2027** or **3 Years** from date signed for Stage I. I understand these fees will be billed by NCPHP directly. In the event my fee is reduced, it will revert to the full amount of **$220** upon working as a licensed professional.

_____ **30.** Following the conclusion of my Stage I contract, a Stage II contract will run for **2 Years,** beginning **6/17/2027**. I understand that I will be charged a monitoring fee of **$110** per month for Stage II. In the event my fee is reduced, it will revert to the full amount upon working as a licensed professional. NCPHP may require further monitoring in the case of relapse of illness or substantial non-compliance as a condition of advocacy. I may elect to continue monitoring if active support is needed beyond the expiration date or at my discretion to support my recovery.

_____ **31.** I agree to provide a copy of this contract to the following:

Therapist _____

Psychiatrist N/A

Workplace advocate _____

_____ **32.** I agree to sign a Consent to Release Confidential Information to NCPHP (Consent B) and a Consent for NCPHP to Disclose Confidential Information to Third Party (Consent A), which are attached to and part of this contract.

_____ _____

Participant Signature Date

_____ _____

NCPHP signature Date

Revised 2-2024

Harsha Ghatge NAGARAJA

License Number:
21552

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Sep-28-2021

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Monroe

Public State:
North Carolina

Public ZIP Code:
[redacted]

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Neurology

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
St. Matthew's University School of Medicine (Grande Cayman)	Medical Doctor Degree	N/A	N/A

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Albany Medical Center	Internship	Internal Medicine	Jul-01-2009	Jun-30-2010

Institution	Program Type	Specialty Type	Start Date	End Date
Albany Medical Center	Residency	Neurology	Jul-01-2010	Jun-30-2013
University of Virginia Medical Center	Fellowship	Neurophysiology	Jul-01-2013	Jun-30-2014

Board Actions

Summary Attachments

None.

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary Attachments

None.

Malpractice Information

Summary Attachments

None.

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11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

[redacted]

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☒ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Rachel Middle: Elizabeth Last: Miceli

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 19715 Specialty: Emergency Medicine

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Ageless Men's Health

Practice Address: 630 Sierra Rose Dr Suite #: A1

City: Reno State: NV Zip: 89509

Telephone: 7754331207 Fax: _____ Email: _____

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

N/P

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/2023	01/2024	IL	Chicago	Cook
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

I voluntarily spent 7 weeks in treatment in 2023 for alcohol use at Positive Sobriety Institute and was cleared back to work and had no actions taken against my job or license. I am currently in good standing under a monitoring contract with the state of Nevada PMP under direct supervision of the medical board. I have included my contract with the monitoring program with this paperwork.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

12/11/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rachel Miceli

Print Name (First, Last)

12/12/2024

Date

[redacted]

Original Signature (electronic, copies or stamps not accepted)

12/12/2024

Date

Board Use Only: Date Processed: 12/19/24 Amount: $200.00

NVPHP Medical Counseling Contract

The NVPHP Medical Counseling Contract is a legal document that specifies the terms under which NVPHP agrees to counsel, aid, and monitor a medical professional within the program. The purpose of this contract is to prevent any misunderstanding of the terms and the time specified. It is specifically designed to meet the needs of the individual. All provisions may not apply to every individual; however, all provisions will apply unless indicated explicitly for the omission.

Provisions of the Contract

1. I agree to the terms of this contract for a period of **Three (3) Years** beginning on **January 12, 2024,** with a reevaluation conducted annually.

2. I understand that all expenses connected with my treatment in the program are my responsibility. The NVPHP monthly fee is $250.00, which includes random urine drug screenings.

3. I agree to participate in the ***Aftercare*** meeting with NVPHP on the first Tuesday of each month and ***Peer Support Group Counseling*** each Wednesday, held at 1800 hours. Participants may be excused only once with prior approval and may miss a maximum of two Peer Group Counseling meetings per year. After the third absence, the governing Nevada State Board will be notified of the event.

4. Counseling/Monitoring agreements are abstinence-based. I agree to abstain from any mood-altering drugs, including alcohol, completely. If a physician prescribes any medications, I will notify NVPHP and provide a copy of the prescription for my file.

5. I agree to pay all financial obligations, including NVPHP monitoring fees.

6. I agree not to manage my own medical care and to comply with the treatment plan, including but not limited to complying with recommendations and not self-prescribing or independently discontinuing medications.

NVPHP Medical Counseling Contract

7. At the discretion of NVPHP, I agree to be evaluated by a psychiatrist/psychologist for a thorough examination and recommendations for therapy at any time during my contract.

8. I agree to have no more than one individual counselor besides the NVPHP Clinical Director.

9. I agree to notify NVPHP within 24 hours of any changes in my physical or mental health, contact information, employer, or any change in work setting.

10. I agree to consent to the release to NVPHP of verbal information and all documentation, including toxicology testing results of visits to emergency treaters, with any third parties such as emergency treaters.

11. I agree to be appropriately courteous and cooperative in all contacts with NVPHP staff and representatives. I agree to return NVPHP calls and e-mails in a timely manner.

12. I agree to submit to random urinalysis screenings as determined by the NVPHP Clinical Program Director. You must report within four hours of notification. In cases where you cannot leave your place of employment, you must report within two hours of your shift ending.

13. I understand that ungloved administration of anesthesia/sedation can produce positive toxicology results. I therefore agree that I will not administer medications without wearing gloves.

14. I agree not to prescribe scheduled drugs for family members or others who are not legitimate patients within the scope of my practice.

NVPHP Medical Counseling Contract

15. I understand that the documentation of my progress will be kept confidential at NVPHP.

16. I understand that this contract is valid for thirty-six (36) months from the date in section one of the agreement or until my termination from the NVPHP program, whichever is later.

17. I understand and agree that my failure to comply with any of this contract's provisions will result in notification to the governing Nevada State Board and my current employer. Furthermore, NVPHP is authorized to furnish the State Board copies of this contract, medical records, drug screen results, and other records pertinent to my treatment and aftercare.

I HAVE READ AND UNDERSTAND ALL OF THE ABOVE INFORMATION:

[redacted] 01-12-2024

Signature Date

[redacted] 01-12-2024

Clinical Program Director Date

POSITIVE
SOBRIETY
INSTITUTE

142 E. Ontario, Suite 1000
Chicago, IL 60611

January 26th, 2024

To Whom It May Concern:

Dr. Rachel Miceli [redacted] was admitted to the Positive Sobriety Institute's Professionals' Program in Chicago, Illinois on 11/27/2023 and was successfully discharged on 01/12/2024. Provided that there is ongoing adherence to her discharge recommendations which include professional monitoring by Community Bridges, Inc. (CBI), recovery meeting attendance, and regular follow ups with invidual therapy and psychiatry, the clinical team at PSI has cleared Dr. Miceli from a substance use disorder/mental health standpoint to return to medical practice as of 1/13/24. When Dr. Miceli returns to practice, a gradual reentry is advised to support her sobriety and mental health.

If there are any further questions or concerns, please feel free to contact me.

Sincerely,

[redacted]

[redacted]
General/Addiction Psychiatry (ABPN), Addiction Medicine (ABPM)
Associate Medical Director, Positive Sobriety Institute
[redacted]

Rachel Elizabeth MICELI

License Number:
19715

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Mar-20-2020

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Sparks

Public State:
Nevada

Public ZIP Code:
[redacted]

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Emergency Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
University of Nevada School of Medicine / Reno, NV	Medical Doctor Degree	N/A	May-23-2017

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
University of Nebraska Medical Center / Omaha, NE	Residency	Emergency Medicine	Jul-01-2017	Aug-31-2020

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
MERCADO, John Paul Bacaltos	Primary Supervisor	Mar-20-2023
HAYS, Kara Nicole	Primary Supervisor	Dec-10-2024

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11C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

[redacted]

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

38157

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Devendrakumar Middle: Ishwarbhai Last: Patel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: M.D. Practitioner License #: 26987 Specialty: Internal Medicine, Cardiology

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any):

Practice Address: 3195 Saint Rose Parkway Suite 212 Suite #: 212

City: Henderson State: NV Zip: 89052

Telephone: 702-342-1384 Fax: Email: [redacted]

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

N - Report Attached

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

As described in response to questions 2 and 3, I was convicted of a felony charge of distributing a controlled substance in Federal District Court. Subsequently, Nevada, New York and Nebraska revoked my medical licenses in part based up that conviction.

D. Patel

Original Signature (electronic, copies or stamps not accepted)

2/17/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Devendrakumar Patel
Print Name (First, Last)

2/3/2025
Date

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/3/2025
Date

Board Use Only: Date Processed: 2/24/25 Amount: $200 CK 138

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/28/2021	08/25/2021	NE	Licoln	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
210661MBBS	State of Nebraska Department of Health and Human Services

Reason/Charge	
Felony Conviction/NV Board Action	
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**
Patel, Devendrakumar	
Name of Business/Industry/Entity	

Provide explanation below:

The Nebraska Medical Board revoked my medical license on September 4, 2021, based on my criminal conviction and the revocation of my Nevada medical license.

A copy of the Petition for Disciplinary Action and Findings of Fact, Conclusions of Law and Order are attached.

D. Patel

Original Signature (electronic, copies or stamps not accepted)

2/17/2025

Date

FILED

AUG 25 2021

DHHS Hearing Offic

STATE OF NEBRASKA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATE OF NEBRASKA ex rel., DOUGLAS J. PETERSON, Attorney General, Plaintiff, v. PATEL, DEVENDRAKUMAR, Defendant.	210661 MBBS FINDINGS OF FACT AND CONCLUSIONS OF LAW; ORDER

STATEMENT OF THE CASE

A Petition for Disciplinary Action was filed in this matter on June 28, 2021, alleging that Defendant, Devendrakumar Patel, was convicted in U.S. District Court of one count of Intentional Distribution of a Controlled Substance without a legitimate medical purpose, and for having his license disciplined in another state or jurisdiction.

SUMMARY OF THE HEARING

A hearing was held in this matter on August 19, 2021, in Lincoln, Nebraska, before Robert E. Harkins, Department of Health and Human Services (DHHS) Hearing Officer. Mindy Lester, Assistant Attorney General, appeared on behalf of the State of Nebraska. Defendant, Devendrakumar Patel, did not appear. Testimony and exhibits were received into evidence.

The Hearing Officer makes the following proposed Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. Proper notice of this hearing was provided to the parties.

2. On March 9, 2000, DHHS issued Physician license #21368 to Defendant, which license expired on October 1, 2004.

3. As a result of a criminal investigation, the United States Department of Justice discovered that between September 2015 and February 2016; Defendant prescribed Oxycodone and Hydrocodone to several of his patients without a legitimate medical purpose and outside the usual course of professional practice.

4. On December 6, 2017, a Grand Jury in the United States District Court for the District of Nevada indicted the Defendant on twenty one counts of Intentional Distribution of a Schedule II Controlled Substance without a legitimate medical purpose, four counts of Intentional Distribution

of a Schedule III Controlled Substance without a legitimate medical purpose, eleven counts of Intentional Distribution of a Schedule IV Controlled Substance without a legitimate medical purpose, and three counts of health care fraud.

5. On May 7, 2019, Defendant pled guilty to one Count of Intentional Distribution of a Schedule II Controlled Substance without a legitimate medical purpose. The Court sentenced defendant to a term of three years and one month in Federal prison, and imposed a fine of $500,000.00.

6. On September 6, 2019, the Nevada Board of Medical Examiners accepted and approved a Settlement Agreement wherein the Board found Defendant had illegally dispensed controlled substances. The Board revoked Defendant's Nevada physician license.

CONCLUSIONS OF LAW

Jurisdiction is based upon Neb. Rev. Stat. §§38-176 and 38-186. A credential to practice may be disciplined for conviction of a misdemeanor or felony under Nebraska law or federal law which has a rational connection with the fitness or capacity of the applicant or credential holder to practice the profession. Neb. Rev. Stat. §38-178(5)(a). Conviction means a plea or verdict of guilty or a conviction following a plea of nolo contendere or non vult contendere made to a formal criminal charge or a judicial finding of guilt irrespective of the pronouncement of judgment or the suspension thereof and includes instances in which the imposition or the execution of sentence is suspended following a judicial finding of guilt and the defendant is placed on probation. Neb. Rev. Stat. §38-177(2).

A credential to practice may also be disciplined for having had a credential denied, refused renewal, limited, suspended, revoked, or disciplined in any manner similar to section 38-196 by another state or jurisdiction based upon acts by the applicant or credential holder similar to acts described in this section. Neb. Rev. Stat. §38-178(12). Upon the completion of any hearing held regarding discipline of a credential, the director may dismiss the action or impose any of the following sanctions: (1) Censure; (2) Probation; (3) Limitation; (4) Civil penalty; (5) Suspension; or (6) Revocation. Neb. Rev. Stat. §38-196.

The practice of medicine is regulated under the Uniform Credentialing Act to protect the health and safety of Nebraska citizens. Neb. Rev. Stat. §38-103. The evidence supports a finding by clear and convincing evidence that the Defendant was convicted of a Federal felony that is not only rationally related to his fitness or capacity to practice his profession, but directly linked to his treatment of patients. The State also proved by clear and convincing evidence that the State of Nevada disciplined Defendant's medical license based on acts similar to those described in Neb.Rev.Stat. §38-178. Both Defendant's Federal felony conviction and the Nevada disciplinary

action constitute grounds for discipline against Defendant's Nebraska license. Revocation is the only suitable remedy to address Defendant's reprehensible conduct, and is the only remedy that will adequately safeguard the health and safety of Nebraska citizens.

ORDER

Based upon the foregoing proposed Findings of Fact and Conclusions of Law, I recommend that the Defendant's license to practice as a physician in the State of Nebraska be REVOKED.

Date: 8/25/21

[redacted]

Robert E. Harkins, Hearing Officer

I hereby adopt the foregoing proposed Findings of Fact and Conclusions of Law and recommended Order in the above captioned proceedings as my official and final Order, and the following sanction is imposed against the Defendant:

Defendant's license to practice as a physician in the State of Nebraska is hereby REVOKED, effective TEN (10) DAYS from the date of this Order.

IT IS SO ORDERED.

Date: 8/25/21

[redacted]

Gary J. Anthone, MD
Chief Medical Officer
Director, Division of Public Health
Department of Health and Human Services

NOTICE

Pursuant to the Administrative Procedure Act, NEB. REV. STAT. § 84-901 *et seq.*, this decision may be appealed by filing a petition in the district court of the county where the action is taken within thirty days after the service of the final decision by the agency.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing was sent on the date below by United States Mail, postage prepaid, and/or electronically to the following:

DEVENDRAKUMAR PATEL
FCI SHERIDAN
FEDERAL CORRECTIONAL INSTITUTION
PO BOX 5000
SHERIDAN OR 97378

MINDY LESTER
ASSISTANT ATTORNEY GENERAL
AGO.HEALTH@NEBRASKA.GOV

Date: August 25, 2021

[redacted]

DHHS Hearing Office
P.O. Box 98914
Lincoln, NE 68509-8914
P. (402) 471-7237 F. (402) 742-2374
dhhs.hearingoffice@nebraska.gov

FILED

JUN 28 2021

DHHS Hearing Offic

STATE OF NEBRASKA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

STATE OF NEBRASKA ex rel. DOUGLAS J. PETERSON, Attorney General, Plaintiff, vs. DEVENDRAKUMAR ISHWARBHAI PATEL, MBBS, Defendant.	)	PETITION FOR DISCIPLINARY ACTION

The Plaintiff alleges as follows:

ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

1. Jurisdiction is based on Neb. Rev. Stat. §§ 38-176 and 38-186 (Reissue 2016).

2. At all times relevant herein, the Defendant, Devendrakumar Ishwarbhai Patel, MBBS, has been the holder of a physician license (#21368) issued by the Department of Health and Human Services Division of Public Health ("Department").

3. The Department is the agency in the State of Nebraska authorized to enforce the provisions of the Uniform Credentialing Act regulating the practice of medicine and surgery.

4. The Nebraska Board of Medicine and Surgery considered the investigation of this matter and made a disciplinary recommendation to the Attorney General, which recommendation has been considered. Such matters are privileged pursuant to Neb. Rev. Stat. §§ 38-1,105 and 38-1,106 (Reissue 2016).

5. On December 6, 2017, the Defendant was indicted in the United States District Court for the District of Nevada for twenty-one counts of intentional distribution of a Schedule II Controlled Substance without a legitimate medical purpose, four counts of intentional distribution of Schedule III Controlled Substances without a legitimate medical purpose, eleven counts of intentional distribution of Schedule IV Controlled Substances without a legitimate medical purpose and three counts of health care fraud.

6. In May 2019, the Defendant entered a plea of guilty to Count 1 of the Indictment and was sentenced to three years and one month in federal prison for distribution of a controlled substance outside the course of his professional practice.

7. On September 6, 2019, the Nevada Board of Medical Examiners accepted and approved a settlement Agreement wherein the Board found the Defendant had illegally dispensed controlled substances. The Defendant's Nevada physician license was revoked. A copy of the Nevada disciplinary documentation is attached as Exhibit "1".

8. The 2019 Nevada disciplinary action was based upon acts by the Defendant similar to those described in the following sections of Neb. Rev. Stat. § 38-178 (2019 Supp.):

a. Neb. Rev. Stat. § 38-178 (5) for conviction of (a) a misdemeanor or felony under Nebraska law or federal law, or (b) a crime in any jurisdiction which, if committed within this state, would have constituted a misdemeanor or felony under Nebraska law and which has a rational connection with the fitness or capacity of the applicant or credential holder to practice the profession; and

b. Neb. Rev. Stat. § 38-178(23) for unprofessional conduct.

FIRST CAUSE OF ACTION

9. Paragraphs 1 through 8 are incorporated herein.

10. Neb. Rev. Stat. § 38-178(11) (2019 Supp.) provides that a professional credential may be disciplined for "having had his or her license credential denied, refused renewal, limited, suspended, revoked or disciplined in any manner similar to section 38-196 by another state or jurisdiction based upon acts of the...credential holder similar to the acts described in this section."

11. The Defendant's 2019 Nevada disciplinary action against his Nevada physician license is grounds for discipline.

SECOND CAUSE OF ACTION

12. Paragraphs 1 through 11 are incorporated herein by reference.

13. Neb. Rev. Stat. § 38-178(5)(a) (Supp. 2019) provides that a professional license may be disciplined for conviction of a misdemeanor or felony under Nebraska law or federal law.

14. The Defendant's 2019 conviction in the United States District Court for the District of Nevada are grounds for discipline.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays that the Chief Medical Officer set this matter for hearing, order appropriate disciplinary action pursuant to Neb. Rev. Stat. 38-196 (Reissue 2016), and tax the costs of this action to the Defendant.

THE STATE OF NEBRASKA, ex rel.
DOUGLAS J. PETERSON, Attorney General,
Plaintiff,

BY: DOUGLAS J. PETERSON, #18146
Attorney General

BY: [redacted]
Mindy L. Lester, #24421
Assistant Attorney General
2115 State Capitol
Lincoln, NE 68509
(402) 471-1815

Attorneys for the Plaintiff.

44-922-6

NEVADA STATE BOARD OF MEDICAL EXAMINERS

Search

Licensee Details

Person Information

Name: Devendrakumar Ishwarbhai PATEL
Address: Northeastern Nevada Cardiology PC
674 N Cedar St
Elko NV 89801
Phone: 7757771213

License Information

License Type: Medical Doctor
License Number: 11068 Status: Revoked
Issue Date: 7/23/2004 Expiration Date: 6/30/2019

Scope of Practice

Scope of Practice: Cardiovascular Diseases

Scope of Practice: Internal Medicine

Education & Training

School:	Medical College M.S. University / Baroda, India
Degree\Certificate:	Medical Doctor Degree
Date Enrolled:	
Date Graduated:	12/1/1981
Scope of Practice:	

School:	Catholic Medical Center / Jamaica, NY
Degree\Certificate:	Residency
Date Enrolled:	7/1/1989
Date Graduated:	6/30/1992
Scope of Practice:	Internal Medicine

School:	American Board of Internal Medicine
Degree\Certificate:	American Board
Date Enrolled:	
Date Graduated:	1/1/1994
Scope of Practice:	Internal Medicine

School:	St. Luke's Rosevelt Hospital / Amsterdam, NY
Degree\Certificate:	Fellowship
Date Enrolled:	7/1/1992
Date Graduated:	6/30/1994
Scope of Practice:	Cardiovasc Diseases

School:	Interfaith Medical Center / Brooklyn, NY
Degree\Certificate:	Fellowship
Date Enrolled:	7/1/1994
Date Graduated:	6/30/1996
Scope of Practice:	Cardiovasc Diseases

School:	American Board of Cardiovascular Diseases
Degree\Certificate:	American Board
Date Enrolled:	
Date Graduated:	1/1/1998
Scope of Practice:	Cardiovasc Diseases

EXHIBIT
2942

CURRENT EMPLOYMENT STATUS/CONDITIONS/RESTRICTIONS ON LICENSE AND MALPRACTICE INFORMATION

PROFESSIONAL LIABILITY CLAIM, SETTLEMENT OR JUDGEMENT OF $5,000 OR MORE: 1)Date received by the Board: 5/3/2016 Reported by: Medicus Ins. Date of act/omission: 10/2/2012 Details:Alleged delayed diagnosis of an MI resulting in unknown damage to a 58 year old male patient Settlement amount: $125,000 Court Case Number:CV-C-13-516 Total pages: 0

Board Actions

SETTLEMENT AGREEMENT Case Nos. 18-29352-1/2/3 09/06/2019 On September 6, 2019, the Nevada State Board of Medical Examiners accepted and approved a Settlement Agreement which allowed for an order to be entered finding Dr. Patel violated NRS 630.306(1)(e), as set forth in Count I of the Complaint in Case No. 18-29352-3, and ordering that his license to practice medicine in Nevada be revoked, and he may not apply for reinstatement of his license for a period of three years; that he receive a public reprimand; and that he reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him, with the order for reimbursement stayed until such time as he reapplies for licensure. All counts of the First Amended Complaints in Case Nos. 18-29352-1 and 18-29352-2 and the remaining counts of the Complaint in Case No. 18-29352-3 shall be dismissed with prejudice. Settlement Agreement: 10 pages COMPLAINT Case # 18-29352-3 12/11/2018 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Dr. Patel alleging three violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.306(1)(e), illegal dispensing of controlled substances; Count II: Alleges a violation of NRS 630.306(1)(p), unsafe or unprofessional conduct; and Count III: Alleges a violation of NRS 630.301(9), disreputable conduct. Complaint: 21 pages FIRST AMENDED COMPLAINT Case # 18-29352-2 February 1, 2018 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal First Amended Complaint against Devendrakumar L. Patel, M.D., alleging three violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4), malpractice. Count II: Alleges a violation of NRS 630.301(7), violating patient?s trust for financial gain. Count III: Alleges a violation of NRS 630.301(8), failure to offer appropriate procedures for financial benefit. FIRST AMENDED COMPLAINT: 7 pages

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FIRST AMENDED COMPLAINT Case # 18-29352-1 February 1, 2018 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal First Amended Complaint against Devendrakumar L. Patel, M.D., alleging one violation of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4), malpractice. FIRST AMENDED COMPLAINT: 5 pages

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COMPLAINT Case # 18-29352-2 January 26, 2018 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Devendrakumar L. Patel, M.D., alleging three violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4), malpractice. Count II: Alleges a violation of NRS 630.301(7), violating patient's trust for financial gain. Count III: Alleges a violation of NRS 630.301(8), failure to offer appropriate procedures for financial benefit. COMPLAINT: 7 pages

****

COMPLAINT Case # 18-29352-1 January 26, 2018 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Devendrakumar L. Patel, M.D., alleging one violation of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4), malpractice. COMPLAINT: 5 pages

Please note that the settlement of a medical malpractice action may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the provider. Therefore, there may be no disciplinary action appearing for a licensee even though there is a closed malpractice claim on file. A payment in the settlement of medical malpractice does not create a presumption that medical malpractice occurred. Sometimes insurance companies settle a case without the knowledge and/or agreement of the physician. This database represents information from insurers to date. Please note: All insurers may not have submitted claim information to the Board.

Close Window

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/14/2020	9/21/2020	NY	Albany	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
BPMC 20-164	New York State, State Board for Professional Medical Conduct

Reason/Charge
Felony Conviction/NV Board Action

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Devendrakumar Ishwarbhai Patel, M.D.	

Name of Business/Industry/Entity

Provide explanation below:

On May 4, 2020, the state of New York summarily suspended my expired New York medical license on the basis of my federal criminal conviction. The expired license was subsequently revoked by New York effective September 21, 2020, based on my federal conviction and the revocation of my Nevada license.

Attached is the Order of Summary Suspension and Order of Revocation

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/17/2025

Date

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

September 14, 2020

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Devendrakumar Ishwarbhai Patel, M.D.
[redacted]

Trudy A. Menard, Esq.
Bureau of Professional Medical Conduct
Corning Tower Building, Room 2512
Empire State Plaza
Albany, New York 12237

RE: In the Matter of Devendrakumar Ishwarbhai Patel, M.D.

Dear Parties:

Enclosed please find the Determination and Order (No. 20-232) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

Five days after receipt of this Order, you will be required to deliver to the Board of Professional Medical Conduct your license to practice medicine together with the registration certificate. Delivery shall be by either certified mail or in person to:

Office of Professional Medical Conduct
New York State Department of Health
Office of Professional Medical Conduct
Riverview Center
150 Broadway - Suite 355
Albany, New York 12204

If your license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, you shall submit an affidavit to that effect. If subsequently you locate the requested items, they must then be delivered to the Office of Professional Medical Conduct in the manner noted above.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), (McKinney Supp. 2015) and §230-c subdivisions 1 through 5, (McKinney Supp. 2015), "the determination of a committee on professional medical conduct may be reviewed by the

Administrative Review Board for professional medical conduct." Either the licensee or the Department may seek a review of a committee determination.

Request for review of the Committee's determination by the Administrative Review Board stays penalties other than suspension or revocation until final determination by that Board. Summary orders are not stayed by Administrative Review Board reviews.

All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

James F. Horan, Esq., Chief Administrative Law Judge
New York State Department of Health
Bureau of Adjudication
Riverview Center
150 Broadway – Suite 510
Albany, New York 12204

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board. Six copies of all papers must also be sent to the attention of Mr. Horan at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

[redacted]

James F. Horan
Chief Administrative Law Judge
Bureau of Adjudication

JFH: cmg
Enclosure

STATE OF NEW YORK: DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

COPY

IN THE MATTER	DETERMINATION
OF	AND
DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.	ORDER
	BPMC-20-232

In accordance with Public Health Law (PHL) §230, and the New York State Administrative Procedure Act (SAPA) Article 3, a hearing was held by videoconference on August 13, 2020. Pursuant to PHL §230(10)(e), William P. Dillon, M.D., Chairperson, Richard F. Kasulke, M.D., and Paul J. Lambiase, duly designated members of the State Board for Professional Medical Conduct (BPMC), served as the Hearing Committee in this matter. Jean T. Carney, Administrative Law Judge (ALJ), served as the Administrative Officer.

The Department appeared by Senior Attorney Trudy A. Menard. The Respondent failed to appear[1]. Jurisdiction over the Respondent was obtained by personal service of the Commissioner's Order of Summary Action, Notice of Referral Proceeding, and Statement of Charges. The Hearing Committee received and examined documents from the Department (Exhibits 1-5). A stenographic reporter prepared a transcript of the

[1] The Respondent was personally served at FCI Sheridan, in Sheridan Oregon, and was given information on how to participate at the hearing remotely; but failed to make any attempt to participate and was found in default. (Exhibit 1; Transcript @ p.7)

proceeding. After consideration of the entire record, the Hearing Committee sustains the charges that the Respondent committed professional misconduct in violation of Educ. Law §§6530(9)(a)(ii) and 6530(9)(d); and that pursuant to PHL §230-a, the penalty of revocation is appropriate.

BACKGROUND

The Department brought the case pursuant to PHL §230(10)(p), which provides for a hearing when a licensee is charged solely with a violation of Educ. Law §6530(9).

The Respondent is charged with professional misconduct pursuant to Educ. Law §6530(9)(a)(ii), having been convicted of committing an act constituting a crime under federal law; and Educ. Law §6530(9)(d), having had disciplinary action taken by a duly authorized professional disciplinary agency of another state, where the conduct resulting in such action would, if committed in New York State, constitute professional misconduct under the laws of New York State.

Under PHL §230(10), the Department had the burden of proving its case by a preponderance of the evidence. Any licensee found guilty of professional misconduct under the procedures prescribed in PHL § 230 "shall be subject to penalties as prescribed in [PHL § 230-a] except that the charges may be dismissed in the interest of justice."

FINDINGS OF FACT

The following findings are the unanimous determinations of the Hearing Committee:

1. The Respondent was authorized to practice medicine in New York State on July 14, 1992, by the issuance of license number 189760. (Exhibit 5).

2. On November 26, 2018, the Respondent executed a Plea Agreement wherein he pled guilty to distributing a controlled substance in violation of 21 U.S.C. §841(a)(1). Specifically, the Respondent knowingly and intentionally distributed Oxycodone without a legitimate medical purpose and outside the course of professional practice. (Exhibit 3).

3. On May 7, 2019, the United States District Court, District of Nevada, sentenced the Respondent to 37 months in prison, with three years of post-release supervision, and $500,000 in fines. (Exhibit 3).

4. On or about July 2, 2019, the Respondent executed a Settlement Agreement with the Board of Medical Examiners of the State of Nevada (NV Board) wherein he admitted to engaging in conduct constituting grounds for professional discipline; namely, in illegally dispensing controlled substances. The NV Board revoked the Respondent's license to practice medicine, and required that he pay the costs and expenses of the investigation, amounting to $10,103.88. (Exhibit 4).

VOTE OF THE HEARING COMMITTEE

The Hearing Committee unanimously concludes that the evidence supports sustaining the charge of having committed misconduct as defined in Educ. Law §6530(9)(a)(ii) and §6530(9)(d).

HEARING COMMITTEE DETERMINATIONS

The Department met its burden of proving by a preponderance of the evidence that the Respondent committed professional misconduct as alleged in the Statement of Charges. The evidence shows that the Respondent was convicted of acts constituting a federal crime resulting in incarceration; and had disciplinary action taken by the NV Board resulting in the revocation of his license to practice medicine for the same conduct. If committed in New York State, the Respondent's actions would establish professional misconduct pursuant to Educ. Law §6530(9)(a)(ii). The committee concludes that the Respondent's actions constitute professional misconduct as defined in Educ. Law §§6530(9)(a)(ii) and 6530(9)(d).

In considering the full spectrum of penalties available by statute, including revocation, suspension and/or probation, censure and reprimand, and the imposition of monetary penalties; the Hearing Committee noted that the Respondent failed to respond to the charges, despite being given the opportunity to do so. The Hearing Committee considered the serious nature of the conviction, and that the Respondent's conduct placed the public at risk of harm. The Hearing Committee agrees with the Department's

recommendation that his medical license in New York State be revoked pursuant to PHL §230-a.

ORDER

IT IS HEREBY ORDERED THAT:

1. The specification of professional misconduct as set forth in the Statement of Charges is sustained;

2. The Respondent's license to practice medicine is revoked; and

3. This Order shall be effective upon service on the Respondent in accordance with the Requirements of PHL §230(10)(h).

DATED: Albany, New York
SEPT 8TH, 2020

[redacted]

William P. Dillon, M.D., Chairperson
Richard F. Kasulke, M.D.
Paul J. Lambiase

To: Devendrakumar Ishwarbhai Patel, M.D.
[redacted]
FCI Sheridan
PO Box 5000
Sheridan, OR 97378

Trudy A. Menard, Esq.
Senior Attorney
Bureau of Professional Medical Conduct
Corning Tower Building – Room 2512
Empire State Plaza
Albany, New York 12237

APPENDIX A

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER
OF
DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.

COMMISSIONER'S ORDER OF SUMMARY ACTION

TO: DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.
FCI Sheridan
PO Box 5000
Sheridan, OR 97378

The undersigned, Marybeth Hefner, Deputy Commissioner for Administration, pursuant to N.Y. Public Health Law §230, and upon the recommendation of a Committee on Professional Medical Conduct of the State Board for Professional Medical Conduct, has determined that Devendrakumar Ishwarbhai Patel, M.D. (henceforth "Respondent"), New York license number 189760, was convicted of committing an act constituting a felony under federal law in the United States District Court, District of Nevada, as is more fully set forth in the Statement of Charges attached to the Notice of Referral Proceeding and made a part hereof.

It is therefore:

ORDERED, pursuant to N.Y. Public Health Law §230(12)(b), that effective immediately, Respondent shall not practice medicine in the State of New York, or practice in any setting under the authority of Respondent's New York license.

> Any practice of medicine in violation of this Order shall constitute Professional Misconduct within the meaning of N.Y. Educ. Law §6530(29) and may constitute unauthorized medical practice, a Felony defined by N.Y. Educ. Law §6512.

This Order shall remain in effect until the final conclusion of a hearing which shall commence within ninety days of the service of this order and shall end within ninety days thereafter. The hearing will be held pursuant to the provisions of N.Y. Pub. Health Law

EXHIBIT
953 2

§230, and N.Y. State Admin. Proc. Act §§301-307 and 401. The hearing will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct on a date and at a location to be set forth in a written Notice of Hearing or Notice of Referral Proceeding provided to the Respondent contemporaneously with this Order.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED, AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET FORTH IN NEW YORK PUBLIC HEALTH LAW §230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATED: Albany, New York.
May 4, 2020

[redacted]
Marybeth Hefner
Deputy Commissioner for Administration
New York State Department of Health

Inquiries should be directed to:

Trudy A. Menard
Senior Attorney
N.Y.S. Department of Health
Division of Legal Affairs
Bureau of Professional Medical Conduct
Corning Tower, Room 2512
Empire State Plaza
Albany, New York 12237
(518) 473-4282
(518) 473-2430 Fax

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF DEVENDRAKUMAR PATEL, M.D.	NOTICE OF REFERRAL PROCEEDING

TO: Devendrakumar Patel, M.D.
[redacted]
FCI Sheridan
27072 Ballston Road
Sheridan, OR 97378

PLEASE TAKE NOTICE THAT:

An adjudicatory proceeding will be held pursuant to the provisions of N.Y. Pub. Health Law §230(10)(p) and N.Y. State Admin. Proc. Act §§301-307 and 401. The proceeding will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct (Committee) on August 13, 2020, at 10:30 a.m., at the offices of the New York State Department of Health, Riverview Center, 150 Broadway, Suite 510, Menands (Albany), NY 12204-2719,[1] or by video conference as directed by the Administrative Law Judge, and at such other adjourned dates, times and places as the committee may direct.

At the proceeding, evidence will be received concerning the allegations set forth in the Statement of Charges, which is attached. A stenographic record of the proceeding will be made and the witnesses at the proceeding will be sworn and examined.

You may appear in person at the proceeding, or by video conference if directed by the Administrative Law Judge, and may be represented by counsel who shall be an attorney admitted to practice in New York state. You may produce evidence or sworn testimony on your behalf. Such evidence or sworn testimony shall be strictly limited to evidence and testimony relating to the nature and severity of the penalty to be imposed upon the licensee. Where the charges are based on the conviction of state law crimes in other jurisdictions, evidence may be offered which would show that the conviction would not be a crime in New York State. The

[1] For GPS purposes, enter "Menands", not "Albany".

Committee also may limit the number of witnesses whose testimony will be received, as well as the length of time any witness will be permitted to testify.

If you intend to present sworn testimony, the number of witnesses and an estimate of the time necessary for their direct examination must be submitted to the New York State Department of Health, Division of Legal Affairs, Bureau of Adjudication, Riverview Center, 150 Broadway - Suite 510, Albany, NY 12204-2719, ATTENTION: HON. JAMES HORAN, DIRECTOR, BUREAU OF ADJUDICATION (Telephone: (518-402-0748), (henceforth "Bureau of Adjudication") as well as the Department of Health attorney indicated below, no later than twenty days prior to the scheduled date of the Referral Proceeding, as indicated above.

Pursuant to the provisions of N.Y. Pub. Health Law §230(10)(p), you shall file a written answer to each of the charges and allegations in the Statement of Charges at least ten days prior to the date of the hearing. Any charge or allegation not so answered shall be deemed admitted: You may wish to seek the advice of counsel prior to filing such answer. You may also file a written brief and affidavits with the Committee. All such documents shall be filed with the Bureau of Adjudication, at the address indicated above, and a copy shall be forwarded to the attorney for the Department of Health whose name appears below, at least ten days prior to the date of the hearing. Should the parties have objection(s) to proposed witnesses or documentary evidence, the party raising the objection(s) shall contact the Bureau of Adjudication at least three days prior to the hearing date to arrange for a pre-hearing conference with the Administrative Law Judge, prior to the hearing date.

Not later than ten days prior to the date of the hearing, you are required to file one copy of your proposed exhibits (if any) with the Bureau of Adjudication at the address indicated above, and a copy of all such documents/exhibits must be served on the same date on the Department of Health attorney indicated below. On the day of the hearing, you are also required to provide the original of such exhibits and three copies, for use by the Committee.

Pursuant to §301(5) of the State Administrative Procedure Act, the Department, upon reasonable notice, will provide at no charge a qualified interpreter of the deaf to interpret the proceedings to, and the testimony of, any deaf person. Pursuant to the terms of N.Y. State Admin. Proc. Act §401 and 10 N.Y.C.R.R. §51.8(b), the Petitioner hereby demands disclosure of the evidence that the Respondent intends to introduce at the hearing, including the names of

witnesses, a list of and copies of documentary evidence and a description of physical or other evidence which cannot be photocopied.

YOU ARE HEREBY ADVISED THAT THE ATTACHED CHARGES WILL BE MADE PUBLIC FIVE BUSINESS DAYS AFTER THEY ARE SERVED.
Department attorney: Initial here [redacted]

The proceeding may be held whether or not you appear. Please note that requests for adjournments must be made in writing to the Bureau of Adjudication, at the address indicated above, with a copy of the request to the attorney for the Department of Health, whose name appears below, at least five days prior to the scheduled date of the proceeding. Adjournment requests are not routinely granted. Claims of court engagement will require detailed affidavits of actual engagement. Claims of illness will require medical documentation. Failure to obtain an attorney within a reasonable period of time prior to the proceeding will not be grounds for an adjournment.

The Committee will make a written report of its findings, conclusions as to guilt, and a determination. Such determination may be reviewed by the administrative review board for professional medical conduct.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED, AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET OUT IN NEW YORK PUBLIC HEALTH LAW §§230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATED: Albany, New York
June 5, 2020

[redacted]
TIMOTHY J. MAHAR
Deputy Counsel
Bureau of Professional Medical Conduct

Inquiries should be addressed to:

Trudy Menard
Senior Attorney
Bureau of Professional Medical Conduct
Corning Tower – Room 2512
Empire State Plaza
Albany, NY 12237
(518) 473-4282

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.	STATEMENT OF CHARGES

DEVENDRAKUMAR ISHWARBHAI PATEL, M.D., the Respondent, was authorized to practice medicine in New York State on or about July 14, 1992, by the issuance of license number 189760 by the New York State Education Department.

FACTUAL ALLEGATIONS

A. On May 7, 2019 Respondent was convicted in the United States District Court, District of Nevada of one count of felony distribution of controlled substances. Respondent was sentenced to thirty-seven (37) months incarceration, three years supervised released, a fee of one hundred ($100.00) dollars and a fine of five hundred thousand ($500,000.00) dollars. The conviction resolved allegations that beginning on or about September 2015 and January 2016 and later dates, Respondent knowingly distributed Schedule II controlled substances, oxycodone and hydrocodone. Respondent distributed the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.

B. On or about September 6, 2019 Respondent entered into a Settlement Agreement with the Nevada Board of Medicine (Board) which resolved three separate formal Board complaints. The Settlement Agreement resulted in the revocation of Respondent's Nevada medical license, prohibiting reapplication for three years, a letter of reprimand and imposed a fine and fees in the amount of $10,103.88. The Settlement Agreement

resolved allegations of malpractice, failure to diagnose, recommending medical procedures not clinically indicated, violating a patient's trust for financial gain, failure to offer appropriate procedures for financial benefit, and the Respondent's conviction in the United States District Court, District of Nevada for the distribution of controlled substance.

C. The conduct resulting in the Nevada disciplinary action against Respondent would constitute misconduct under the laws of New York State pursuant to the following sections of New York State law:

1. New York Education Law § 6530(3) (negligence on more than one occasion);

2. New York Education Law § 6530(17) (exercising undue influence on the patient, including the promotion of the sale of services, goods, appliances, or, drugs in such a manner as to exploit the patient for the financial gain of the licensee);

3. New York Education Law § 6530(20) (moral unfitness to practice medicine);

4. New York Education § 6530(9)(a)(ii) (having been convicted of committing an act constituting a crime under federal law).

FIRST SPECIFICATION OF CHARGES

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(a)(ii) by having been convicted of committing an act constituting a crime under federal law as alleged in the facts of the following:

A. The facts in paragraph A.

SECOND SPECIFICATION OF CHARGES

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(d) by having his or her license to practice medicine revoked, suspended or having other disciplinary action taken, or having his or her application for a license refused, revoked or suspended or having voluntarily or otherwise surrendered his or her license after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state, where the conduct resulting in the revocation, suspension or other disciplinary action involving the license or refusal, revocation or suspension of an application for a license or the surrender of the license would, if committed in New York state, constitute professional misconduct under the laws of New York state (namely N.Y. Educ. Law § 6530(3) § 6530(9)(a)(ii) § 6530(17) § 6530(20)) as alleged in the facts of the following:

B. Paragraphs B and C.

DATE: May 5, 2020
Albany, New York

[redacted]

TIMOTHY J. MAHAR
Deputy Counsel
Bureau of Professional Medical Conduct

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

BPMC No. 20-164

IN THE MATTER
OF
DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.

COMMISSIONER'S ORDER OF SUMMARY ACTION

TO: DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.
[redacted]

The undersigned, Marybeth Hefner, Deputy Commissioner for Administration, pursuant to N.Y. Public Health Law §230, and upon the recommendation of a Committee on Professional Medical Conduct of the State Board for Professional Medical Conduct, has determined that Devendrakumar Ishwarbhai Patel, M.D. (henceforth "Respondent"), New York license number 189760, was convicted of committing an act constituting a felony under federal law in the United States District Court, District of Nevada, as is more fully set forth in the Statement of Charges attached to the Notice of Referral Proceeding and made a part hereof.

It is therefore:

ORDERED, pursuant to N.Y. Public Health Law §230(12)(b), that effective immediately, Respondent shall not practice medicine in the State of New York, or practice in any setting under the authority of Respondent's New York license.

Any practice of medicine in violation of this Order shall constitute Professional Misconduct within the meaning of N.Y. Educ. Law §6530(29) and may constitute unauthorized medical practice, a Felony defined by N.Y. Educ. Law §6512.

This Order shall remain in effect until the final conclusion of a hearing which shall commence within ninety days of the service of this order and shall end within ninety days thereafter. The hearing will be held pursuant to the provisions of N.Y. Pub. Health Law

§230, and N.Y. State Admin. Proc. Act §§301-307 and 401. The hearing will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct on a date and at a location to be set forth in a written Notice of Hearing or Notice of Referral Proceeding provided to the Respondent contemporaneously with this Order.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED, AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET FORTH IN NEW YORK PUBLIC HEALTH LAW §230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATED: Albany, New York
May 7, 2020

[redacted]
Marybeth Hefner
Deputy Commissioner for Administration
New York State Department of Health

Inquiries should be directed to:

Trudy A. Menard
Senior Attorney
N.Y.S. Department of Health
Division of Legal Affairs
Bureau of Professional Medical Conduct
Corning Tower, Room 2512
Empire State Plaza
Albany, New York 12237
(518) 473-4282
[redacted]

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF DEVENDRAKUMAR PATEL, M.D.	NOTICE OF REFERRAL PROCEEDING

TO: Devendrakumar Patel, M.D.
[redacted]

PLEASE TAKE NOTICE THAT:

An adjudicatory proceeding will be held pursuant to the provisions of N.Y. Pub. Health Law §230(10)(p) and N.Y. State Admin. Proc. Act §§301-307 and 401. The proceeding will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct (Committee) on August 13, 2020, at 10:30 a.m., at the offices of the New York State Department of Health, Riverview Center, 150 Broadway, Suite 510, Menands (Albany), NY 12204-2719[1], or by video conference as directed by the Administrative Law Judge, and at such other adjourned dates, times and places as the committee may direct.

At the proceeding, evidence will be received concerning the allegations set forth in the Statement of Charges, which is attached. A stenographic record of the proceeding will be made and the witnesses at the proceeding will be sworn and examined.

You may appear in person at the proceeding, or by video conference if directed by the Administrative Law Judge, and may be represented by counsel who shall be an attorney admitted to practice in New York state. You may produce evidence or sworn testimony on your behalf. Such evidence or sworn testimony shall be strictly limited to evidence and testimony relating to the nature and severity of the penalty to be imposed upon the licensee. Where the charges are based on the conviction of state law crimes in other jurisdictions, evidence may be offered which would show that the conviction would not be a crime in New York State. The

[1] For GPS purposes, enter "Menands", not "Albany"

Committee also may limit the number of witnesses whose testimony will be received, as well as the length of time any witness will be permitted to testify.

If you intend to present sworn testimony, the number of witnesses and an estimate of the time necessary for their direct examination must be submitted to the New York State Department of Health, Division of Legal Affairs, Bureau of Adjudication, Riverview Center, 150 Broadway - Suite 510, Albany, NY 12204-2719, ATTENTION: HON. JAMES HORAN, DIRECTOR, BUREAU OF ADJUDICATION [redacted] henceforth "Bureau of Adjudication") as well as the Department of Health attorney indicated below, no later than twenty days prior to the scheduled date of the Referral Proceeding, as indicated above.

Pursuant to the provisions of N.Y. Pub. Health Law §230(10)(p), you shall file a written answer to each of the charges and allegations in the Statement of Charges at least ten days prior to the date of the hearing. Any charge or allegation not so answered shall be deemed admitted. You may wish to seek the advice of counsel prior to filing such answer. You may also file a written brief and affidavits with the Committee. All such documents shall be filed with the Bureau of Adjudication, at the address indicated above, and a copy shall be forwarded to the attorney for the Department of Health whose name appears below, at least ten days prior to the date of the hearing. Should the parties have objection(s) to proposed witnesses or documentary evidence, the party raising the objection(s) shall contact the Bureau of Adjudication at least three days prior to the hearing date to arrange for a pre-hearing conference with the Administrative Law Judge, prior to the hearing date.

Not later than ten days prior to the date of the hearing, you are required to file one copy of your proposed exhibits (if any) with the Bureau of Adjudication at the address indicated above, and a copy of all such documents/exhibits must be served on the same date on the Department of Health attorney indicated below. On the day of the hearing, you are also required to provide the original of such exhibits and three copies, for use by the Committee.

Pursuant to §301(5) of the State Administrative Procedure Act, the Department, upon reasonable notice, will provide at no charge a qualified interpreter of the deaf to interpret the proceedings to, and the testimony of, any deaf person. Pursuant to the terms of N.Y. State Admin. Proc. Act §401 and 10 N.Y.C.R.R. §51.8(b), the Petitioner hereby demands disclosure of the evidence that the Respondent intends to introduce at the hearing, including the names of

witnesses, a list of and copies of documentary evidence and a description of physical or other evidence which cannot be photocopied.

YOU ARE HEREBY ADVISED THAT THE ATTACHED CHARGES WILL BE MADE PUBLIC FIVE BUSINESS DAYS AFTER THEY ARE SERVED.

Department attorney initial here [redacted]

The proceeding may be held whether or not you appear. Please note that requests for adjournments must be made in writing to the Bureau of Adjudication, at the address indicated above, with a copy of the request to the attorney for the Department of Health, whose name appears below, at least five days prior to the scheduled date of the proceeding. Adjournment requests are not routinely granted. Claims of court engagement will require detailed affidavits of actual engagement. Claims of illness will require medical documentation. Failure to obtain an attorney within a reasonable period of time prior to the proceeding will not be grounds for an adjournment.

The Committee will make a written report of its findings, conclusions as to guilt, and a determination. Such determination may be reviewed by the administrative review board for professional medical conduct.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED, AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET OUT IN NEW YORK PUBLIC HEALTH LAW §6230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATED: Albany, New York
June 5, 2020

[redacted]
TIMOTHY J. MAHAR
Deputy Counsel
Bureau of Professional Medical Conduct

Inquiries should be addressed to:

Trudy Menard
Senior Attorney
Bureau of Professional Medical Conduct
Corning Tower – Room 2512
Empire State Plaza
Albany, NY 12237
(518) 473-4282

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF DEVENDRAKUMAR ISHWARBHAI PATEL, M.D.	STATEMENT OF CHARGES

DEVENDRAKUMAR ISHWARBHAI PATEL, M.D., the Respondent, was authorized to practice medicine in New York State on or about July 14, 1992, by the issuance of license number 189760 by the New York State Education Department.

FACTUAL ALLEGATIONS

A. On May 7, 2019 Respondent was convicted in the United States District Court, District of Nevada of one count of felony distribution of controlled substances. Respondent was sentenced to thirty-seven (37) months incarceration, three years supervised released, a fee of one hundred ($100.00) dollars and a fine of five hundred thousand ($500,000.00) dollars. The conviction resolved allegations that beginning on or about September 2015 and January 2016 and later dates, Respondent knowingly distributed Schedule II controlled substances, oxycodone and hydrocodone. Respondent distributed the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.

B. On or about September 6, 2019 Respondent entered into a Settlement Agreement with the Nevada Board of Medicine (Board) which resolved three separate formal Board complaints. The Settlement Agreement resulted in the revocation of Respondent's Nevada medical license, prohibiting reapplication for three years, a letter of reprimand and imposed a fine and fees in the amount of $10,103.88. The Settlement Agreement

resolved allegations of malpractice, failure to diagnose, recommending medical procedures not clinically indicated, violating a patient's trust for financial gain, failure to offer appropriate procedures for financial benefit, and the Respondent's conviction in the United States District Court, District of Nevada for the distribution of controlled substance.

C. The conduct resulting in the Nevada disciplinary action against Respondent would constitute misconduct under the laws of New York State pursuant to the following sections of New York State law:

1. New York Education Law § 6530(3) (negligence on more than one occasion);

2. New York Education Law § 6530(17) (exercising undue influence on the patient, including the promotion of the sale of services, goods, appliances, or, drugs in such a manner as to exploit the patient for the financial gain of the licensee);

3. New York Education Law § 6530(20) (moral unfitness to practice medicine);

4. New York Education § 6530(9)(a)(ii) (having been convicted of committing an act constituting a crime under federal law);

FIRST SPECIFICATION OF CHARGES

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(a)(ii) by having been convicted of committing an act constituting a crime under federal law as alleged in the facts of the following:

A. The facts in paragraph A.

SECOND SPECIFICATION OF CHARGES

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(d) by having his or her license to practice medicine revoked, suspended or having other disciplinary action taken, or having his or her application for a license refused, revoked or suspended or having voluntarily or otherwise surrendered his or her license after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state, where the conduct resulting in the revocation, suspension or other disciplinary action involving the license or refusal, revocation or suspension of an application for a license or the surrender of the license would, if committed in New York state, constitute professional misconduct under the laws of New York state (namely N.Y. Educ. Law § 6530(3) § 6530(9)(a)(i) § 6530(17) § 6530(20)) as alleged in the facts of the following:

B. Paragraphs B and C.

DATE: May 5, 2020
Albany, New York

[redacted]

TIMOTHY J. MAHAR
Deputy Counsel
Bureau of Professional Medical Conduct

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/11/18	09/06/19	NV	Reno	Washoe

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
BME 18-29352-1; -2; -3	Nevada State Board of Medical Examiners

Reason/Charge
Malpractice/Illegal Dispensing of Controlled Substance/Unsafe or Unprofessional Conduct/Disreputable Conduct/Financial

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Devendrakumar I Patel, M.D.	

Name of Business/Industry/Entity

Provide explanation below:

On September 6, 2019, the Nevada Board approved and adopted a settlement agreement which resolved three outstanding formal disciplinary complaints (18-29352-1, 18-29352-2, 18-29352-3). Pursuant to the terms of the settlement, I admitted to Count I of Complaint no 18-29352-3, Illegal Dispensing of Controlled Substance (a violation of NRS 630.360(1)(c)). My license was revoked, and I was prohibited from applying for reinstatement of my license for three years. I was also required to pay the fees and costs in the matter totaling $10,103.88 and was issued a public reprimand.

A copy of the Settlement and Complaints is attached.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/17/2025

Date

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against DEVENDRAKUMAR I. PATEL, M.D., Respondent.	**Case No. 18-29352-1**

FILED
FEB - 1 2018
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

FIRST AMENDED COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Devendrakumar I. Patel, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent is a physician licensed to practice medicine in the State of Nevada (License No. 11068). He was originally licensed by the Board on July 23, 2004.

2. Patient A was a 58-year-old male when he presented to Respondent for medical care on October 2, 2012. Patient A's true identity is not disclosed herein to protect his privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

3. On October 2, 2012, Patient A presented to Respondent with signs and symptoms of an ST[2] elevation myocardial infarction (STEMI) of the inferior wall. Despite ample medical evidence available to him, Respondent failed to properly assess and diagnose the STEMI on October 2, 2012.

4. Based on the medical evidence available to him, specifically, ongoing clinical and ECG changes consistent with ischemia, Respondent failed to order urgent cardiac revascularization at a facility

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time the filing of the Complaint was approved, was composed of Theodore B. Berndt, M.D., Wayne Hardwick, M.D., and Mr. M. Neil Duxbury.
[2] In electrocardiography, the "ST" segment connects the QRS complex and the T wave and has a duration of 0.005 to 0.150 sec (5 to 150 ms). ST elevation may indicate transmural myocardial infarction.

capable of rapid revascularization, including Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG), for Patient A on October 2, 2012.

COUNT I

NRS 630.301(4) (Malpractice)

5. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

6. Malpractice is grounds for disciplinary action against a licensee pursuant to NRS 630.301(4).

7. NAC 630.040 defines malpractice as the failure to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances when treating a patient.

8. As demonstrated by, but not limited to, the above-outlined facts, Respondent committed malpractice with respect to his treatment of Patient A.

9. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine the sanctions it will impose if it finds Respondent violated the Medical Practice Act;

4. That the Board make, issue and serve upon the Respondent, in writing, its findings of fact, conclusions of law and order, which shall include the sanctions imposed; and

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5. That the Board take such other and further action as may be just and proper in these premises.

DATED this 1 day of February, 2018.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [redacted]

Robert Kilroy, Esq., General Counsel
Aaron Bart Fricke, Esq., Deputy General Counsel
Donald K. White, Esq., Deputy General Counsel
Attorneys for the Investigative Committee

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF WASHOE)

Wayne Hardwick, M.D., hereby deposes and states under penalty of perjury under the laws of the State of Nevada that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the foregoing First Amended Complaint against the Respondent herein; that he has read the foregoing First Amended Complaint; and based upon information discovered during the course of the investigation into a complaint against Respondent, he believes the allegations and charges in the foregoing First Amended Complaint against Respondent are true, accurate and correct.

DATED this 1st day of February, 2018.

[redacted]

Wayne Hardwick, M.D.
Chairman, Investigative Committee
Nevada State Board of Medical Examiners

CERTIFICATE OF SERVICE

I hereby certify that I am employed by the Nevada State Board of Medical Examiners and that on the 1st day of February, 2018, I served a file-stamped copy of the FIRST AMENDED COMPLAINT and PATIENT DESIGNATION, via USPS e-certified return receipt mail **(9171 9690 0935 0096 2374 00)** to the following:

Devendrakumar I. Patel, M.D.
[redacted]

DATED this 1st day of February, 2018.

[redacted]
Kimberly Rosling, Employee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against DEVENDRAKUMAR I. PATEL, M.D., Respondent.	**Case No. 18-29352-2**

FILED
FEB - 1 2018
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

FIRST AMENDED COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Devendrakumar I. Patel, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent is a physician licensed to practice medicine in the State of Nevada (License No. 11068). He was originally licensed by the Board on July 23, 2004.

A. Enhanced External Counterpulsation (EECP) for the Treatment of Angina

2. EECP is a noninvasive therapy developed for the treatment of end-stage angina pectoris that is refractory to conventional therapy (i.e., surgery, angioplasty) for acute myocardial infarction and cardiogenic shock. EECP involves the sequential compression (inflation/deflation) of cuffs wrapped around the patient's calves, thighs, and buttocks. By timing the inflation/deflation sequence to the patient's cardiac cycle, the intention of EECP is to increase diastolic aortic pressure, thereby increasing coronary perfusion pressure possibly by enhancing the development of coronary collateral circulation and reducing the workload of the heart. Treatment

[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time the filing of the Complaint was approved, was composed of Theodore B. Berndt, M.D., Wayne Hardwick, M.D., and Mr. M. Neil Duxbury.

usually consists of one-hour sessions, five days a week, for seven weeks. EECP has been approved by the U.S. Food and Drug Administration (FDA) for management of refractory angina.

3. End-stage angina pectoris is defined as "disabling angina" (class III or class IV), and is indicted for those who, in the opinion of a cardiologist or a cardiovascular surgeon, are not readily amenable to surgical intervention.

4. Angina is the sensation of chest pain or pressure often with radiation to the left arm or jaw that comes on with exertion or stress and is relieved with rest or medication. It can feel like smothering shortness of breath or severe indigestion. It is caused when the heart muscle outworks its blood supply.

5. Chronic stable angina is the occurrence of angina with predictable levels of exertion, usually lasting less than five minutes. It is reproducible and usually is predictable.

B. Respondent's Treatment of Patient A

6. Patient A was a 71-year-old female when she presented to Respondent for medical care in November 2013. Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

7. On November 8, 2013, Patient A presented to Respondent with progressively increasing malaise, fatigue, and shortness of breath at less than normal exertion. Patient A had a history of coronary artery disease, diabetes, hypertension, hyperlipidemia, rheumatoid arthritis, chronic pain, osteoarthritis, hypothyroidism, and prior deep venous thrombosis, and lived a sedentary lifestyle. A stress test was conducted on November 13, 2013, which was abnormal. A left heart catheterization, selective coronary artery angiography, and left ventriculogram were performed at Northeastern Nevada Regional Hospital on November 10, 2013, which revealed substantial coronary artery disease. Accordingly, coronary artery bypass surgery (CABG) was performed in Salt Lake City, Utah, on December 18, 2013.

8. On July 18, 2014, Patient A presented to Respondent again for progressively increasing shortness of breath and fatigue at less than usual exertion over the past 5-6 years, and recent back pain and low blood pressure. Respondent recommended EECP therapy, and Patient A

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

underwent EECP therapy at Respondent's medical practice during August and September 2014. Respondent billed Patient A $600 for each session, for at least seventeen sessions, for a total of $10,200.

9. Based on the medical evidence available to him, specifically, without an assessment for and diagnosis of angina or angina class (such as how far Patient A could walk before symptoms occur, or other physical assessments), without evidence of how Patient A had responded to standard therapies or treatments, such as CABG, and without assessment or changes in symptoms following CABG, the use of and recommendation of EECP was not indicated.

10. On information and belief, Respondent's conduct in recommending and performing EECP on Patient A was intentional, and made for his own financial benefit and pecuniary gain.

COUNT I

NRS 630.301(4) (Malpractice)

11. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

12. Malpractice is grounds for disciplinary action against a licensee pursuant to NRS 630.301(4).

13. NAC 630.040 defines malpractice as the failure to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances when treating a patient.

14. As demonstrated by, but not limited to, the above-outlined facts, Respondent committed malpractice with respect to his treatment of Patient A by failing to use reasonable care, skill or knowledge in recommending and performing EECP on Patient A.

15. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.301(7) (Violating Patient's Trust for Financial Gain)

16. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

17. Engaging in conduct that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain is grounds for disciplinary action against a licensee pursuant to NRS 630.301(7).

18. As demonstrated by, but not limited to, the above-outlined facts, Respondent violated Patient A's trust and exploited their physician-patient relationship for financial gain recommending, performing and billing for EECP.

19. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.301(8) (Failure to Offer Appropriate Procedures for Financial Benefit)

20. All of the allegations in the above paragraphs are hereby incorporated as if fully set forth herein.

21. The failure to offer appropriate procedures or studies, when the failure occurs with the intent of positively influencing the financial well-being of the practitioner, is grounds for disciplinary action against a licensee pursuant to NRS 630.301(8).

22. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to offer appropriate procedures to Patient A; rather, Respondent offered inappropriate procedures to Patient A by recommending, performing, and billing for EECP, and did so with the intent of positively influencing his own financial well-being.

23. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

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Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

3. That the Board determine the sanctions it will impose if it finds Respondent violated the Medical Practice Act;

4. That the Board make, issue and serve upon the Respondent, in writing, its findings of fact, conclusions of law and order, which shall include the sanctions imposed; and

5. That the Board take such other and further action as may be just and proper in these premises.

DATED this 1 day of February, 2018.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [redacted]

Robert Kilroy, Esq., General Counsel
Aaron Bart Fricke, Esq., Deputy General Counsel
Donald K. White, Esq., Deputy General Counsel
Attorneys for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF WASHOE)

Wayne Hardwick, M.D., hereby deposes and states under penalty of perjury under the laws of the State of Nevada that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the foregoing First Amended Complaint against the Respondent herein; that he has read the foregoing First Amended Complaint; and based upon information discovered during the course of the investigation into a complaint against Respondent, he believes the allegations and charges in the foregoing First Amended Complaint against Respondent are true, accurate and correct.

DATED this 1st day of February, 2018.

[redacted]

Wayne Hardwick, M.D.
Chairman, Investigative Committee
Nevada State Board of Medical Examiners

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

CERTIFICATE OF SERVICE

I hereby certify that I am employed by the Nevada State Board of Medical Examiners and that on the 1st day of February, 2018, I served a file-stamped copy of the FIRST AMENDED COMPLAINT and PATIENT DESIGNATION, via USPS e-certified return receipt mail **(9171 9690 0935 0096 2374 00)** to the following:

Devendrakumar I. Patel, M.D.
[redacted]

DATED this 1st day of February, 2018.

[redacted]

Kimberly Rosling, Employee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
1105 Terminal Way #301
Reno, Nevada 89502
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against DEVENDRAKUMAR I. PATEL, M.D., Respondent.	**Case No. 18-29352-3**

FILED
DEC 11 2018
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Devendrakumar I. Patel, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent is a physician and holds an inactive license to practice medicine in the State of Nevada (License No. 11068). He was originally licensed by the Board on July 23, 2004.

A. Respondent Criminal Conduct

2. Pursuant to a Grand Jury Indictment filed on December 6, 2017 (hereinafter, the "Indictment"), in the U.S. District Court for the State of Nevada, in Criminal Case No. 3:17-cr-00114 LRH-VPC, "USA v. Patel M.D." (hereinafter, the "Federal Case"), a federal grand jury charged Respondent with 39 crimes, as follows: violation of 21 USC 841(a)(1) - Distribution of Controlled Substances - Schedule II (count 1); violation of 21 USC 841(a)(1) - Distribution of Controlled Substances - Schedule II (counts 2-21); violation of 21 USC 841(a)(1) - Distribution of Controlled Substances - Schedule III (counts 22-25); violation of 21 USC 841(a)(1) - Distribution

[1] The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), at the time this formal Complaint was authorized for filing, was composed of Board members Wayne Hardwick, M.D., Chairman, Mr. M. Neil Duxbury, and Aury Nagy, M.D.

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of Controlled Substances - Schedule IV (counts 26-36); violation of 18 USC 1347 - Health Care Fraud (counts 37-39).

3. Pursuant to 18 USC 3559(a)(3), violation of 21 USC 841(a)(1), as alleged in Count One of the Indictment, constitutes a Class C felony.

4. Respondent and his attorney in the Federal Case, Lance Maningo, Esq., along with attorneys for the United States, entered into a "Plea Agreement Under Fed. R. Crim. P. 11 (c)(1)(A) and (B)," filed on November 26, 2018 ("Plea Agreement"), a true and correct copy of which is attached hereto as Exhibit 1 and incorporated herein by this reference. Pursuant to the Plea Agreement, Respondent knowingly and voluntarily agreed to plead guilty to Count One of the Indictment. Specifically, Respondent admitted the following:

a. Count One: The elements of Distribution of Controlled Substance in violation of 21 USC 841(a)(1) and (b)(1)(C) are:

i. First, beginning on or about September 2015 and January 2016 and later dates, the Respondent knowingly distributed Schedule II controlled substances, to wit Oxycodone and Hydrocodone;

ii. Second, the Respondent knew that the controlled substances were Oxycodone and Hydrocodone or some other prohibited drug;

iii. Third, the Respondent distributed the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose; and

iv. Fourth, the Respondent intended to distribute the controlled substances outside the course of his professional practice.

5. Pursuant to the Plea Agreement, Respondent also admitted that he is, in fact and under the law, guilty of the crimes charged, and that he acknowledges that if he elected to go to trial instead of pleading guilty, the United States could prove his guilt beyond a reasonable doubt. Respondent further acknowledges that his admissions and declarations of fact set forth in the Plea Agreement satisfy every element of the charged offense.

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COUNT I

NRS 630.306(1)(c) (Illegal Dispensing of Controlled Substances)

6. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

7. Pursuant to NRS 630.306(1)(c), dispensing any controlled substance to others except as authorized by law is grounds for disciplinary action against a licensee.

8. As demonstrated by, but not limited to, the above-outlined facts, Respondent knowingly and intentionally dispensed controlled substances, Oxycodone and Hydrocodone, outside the usual course of his professional practice and not for a legitimate medical purpose, in violation of 21 USC 841(a)(1) and (b)(1)(C).

9. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.306(1)(p) (Unsafe or Unprofessional Conduct)

10. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

11. Engaging in any act that is unsafe or unprofessional conduct in accordance with regulations adopted by the Board is grounds for disciplinary action against a licensee pursuant to NRS 630.306(1)(p).

12. As demonstrated by, but not limited to, the above-outlined facts, Respondent knowingly and intentionally dispensed controlled substances, Oxycodone and Hydrocodone, outside the usual course of his professional practice and not for a legitimate medical purpose.

13. Respondent's conduct was unsafe and unprofessional.

14. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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COUNT III

NRS 630.301(9) (Disreputable Conduct)

15. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

16. Conduct that brings the medical profession into disrepute is grounds for discipline pursuant to NRS 630.301(9), including, without limitation, conduct that violates any provision of a code of ethics adopted by the Board by regulation based on a national code of ethics.

17. As demonstrated by, but not limited to, the above-outlined facts, Respondent's conduct, under the circumstances set forth herein, constitutes engaging in conduct that brings the medical profession into disrepute.

18. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

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///

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5. That the Board take such other and further action as may be just and proper in these premises.

DATED this 11th day of December, 2018.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [redacted]
Aaron Bart Fricke, Esq., Deputy General Counsel
Attorney for the Investigative Committee

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

VERIFICATION

STATE OF NEVADA)
ss.
COUNTY OF WASHOE)

Wayne Hardwick, M.D., having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 11th day of December, 2018.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

[redacted]

Wayne Hardwick, M.D., Chairman

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

FILED ___ RECEIVED
___ ENTERED ___ SERVED ON
COUNSEL/PARTIES OF RECORD
NOV 26 2018
CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: ___ DEPUTY

DAYLE ELIESON
United States Attorney
SUE FAHAMI
Nevada Bar Number 5634
KILBY MACFADDEN
Assistant United States Attorneys
400 S. Virginia Street, Suite 900
Reno, Nevada 89501
Telephone: (775) 784-5438
Email: kilby.macfadden@usdoj.gov
Representing the United States of America

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
-oOo-

UNITED STATES OF AMERICA,

Plaintiff,

vs.

DEVENDRA I. PATEL, M.D.,

Defendant.

Case No.: 3:17-cr-114 LRH-VPC

PLEA AGREEMENT UNDER FED. R. CRIM. P. 11 (c)(1)(A) and (B)

Plaintiff United States of America, by and through DAYLE ELIESON, United States Attorney, and SUE FAHAMI and KILBY MACFADDEN, Assistant United States Attorneys, the Defendant, DEVENDRA I. PATEL, M.D. and the Defendant's attorney, LANCE MANINGO, ESQ., submit this Plea Agreement under Fed. R. Crim. P. 11(c)(1)(A) and (B).

I. SCOPE OF AGREEMENT

The parties to this Plea Agreement are the United States of America and DEVENDRA I. PATEL (the Defendant). This Plea Agreement binds the Defendant and the United States Attorney's Office for the District of Nevada. It does not bind any other prosecuting, administrative, or regulatory authority, the United States

Probation Office, or the Court.

The Plea Agreement sets forth the parties' agreement regarding criminal charges referenced in the Plea Agreement and applicable sentences, fines, restitution and forfeiture. It does not control or prohibit the United States or any agency or third party from seeking any other civil or administrative remedies directly or indirectly against the Defendant.

II. DISPOSITION OF CHARGES AND WAIVER OF TRIAL RIGHTS

A. Guilty Plea. The Defendant knowingly and voluntarily agrees to plead guilty to Count One of the Criminal Indictment filed December 6, 2017:

Count One: Distribution of a Controlled Substance, in violation of Title 21, United States Code, Section 841(a)(1) and (b)(1)(C).

At the time of sentencing, the Government will move to dismiss the remaining counts of the Criminal Indictment.

B. Waiver of Trial Rights. The Defendant acknowledges that he has been advised and understands that by entering a plea of guilty he is waiving -- that is, giving up -- certain rights guaranteed to all Defendants by the laws and the Constitution of the United States. Specifically, the Defendant is giving up:

1. The right to proceed to trial by jury on all charges, or to a trial by a judge if the Defendant and the United States both agree;

2. The right to confront the witnesses against the Defendant at such a trial, and to cross-examine them;

3. The right to remain silent at such a trial, with assurance that his silence could not be used against him in any way;

4. The right to testify in his own defense at such a trial if he so chooses;

5. The right to compel witnesses to appear at such a trial and testify in the Defendant's behalf, and;

6. The right to have the assistance of an attorney at all stages of such proceedings.

C. Withdrawal of Guilty Plea. The Defendant will not seek to withdraw his guilty plea after he has entered it in court.

D. Additional Charges. The United States agrees not to bring any additional charges against the Defendant arising out of the investigation in the District of Nevada which culminated in the Criminal Indictment and this Plea Agreement and based on conduct known to the United States, except that the United States reserves the right to prosecute the Defendant for any crime of violence as defined by 18 U.S.C. § 16 in which the Defendant may have participated.

III. ELEMENTS OF THE OFFENSE

Count One: The elements of Distribution of Controlled Substance in violation of 21 U.S.C. §§ 841(a)(1) and (b)(1)(C) are:

First, beginning on or about September 2015 and January 2016 and later dates, the Defendant knowingly distributed Schedule II controlled substances, to wit: Oxycodone and Hydrocodone;

Second, the Defendant knew that the controlled substances were Oxycodone and Hydrocodone or some other prohibited drug;

Third, the Defendant distributed the controlled substances outside the usual

course of professional practice and not for a legitimate medical purpose; and

Fourth, the Defendant intended to distribute the controlled substances outside the course of his professional practice.

Ninth Cir. Model Criminal Jury Instr., Criminal 9.18; Title 21 C.F.R. § 1306.04; *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006)

IV. FACTS SUPPORTING GUILTY PLEA

A. The Defendant will plead guilty because he is, in fact and under the law, guilty of the crimes charged.

B. The Defendant acknowledges that if he elected to go to trial instead of pleading guilty, the United States could prove his guilt beyond a reasonable doubt and establish its right to forfeit the specified property by preponderance of the evidence. The Defendant further acknowledges that his admissions and declarations of fact set forth below satisfy every element of the charged offense.

C. The Defendant waives any potential future claim that the facts he admitted in this Plea Agreement were insufficient to satisfy the elements of the charged offense.

D. Both the United States and the Defendant agree that this section of the Plea Agreement does not contain all of the relevant information known to the Defendant. The parties also agree that the facts contained in Section IV provide a sufficient factual basis for the crime to which Defendant is pleading guilty, but the facts contained in Section IV are not an exhaustive statement by the Defendant.

E. The Defendant admits and declares under penalty of perjury that the facts set forth below are true and correct:

At all times relevant to the Criminal Indictment:

1. The Defendant, DEVENDRA I. PATEL, M.D. ("Defendant"), was a licensed physician who, since 2004, practiced medicine in Nevada under Nevada License Number 11068, specializing in cardiology in Elko, Nevada.

2. As part of his medical practice, he prescribed Schedule II Controlled Substances, including Hydrocodone and Oxycodone, under a Drug Enforcement Administration ("DEA") license number BP6740662.

3. Defendant knew that under the Controlled Substances Act, Title 21, United States Code, Section 841(a) *et seq.*, and Title 21, Code of Federal Regulations, Section 1306.04, a prescription for a Schedule II controlled substance was lawful only when written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

4. Between approximately September 2015 and January 2016 and later dates, Defendant prescribed dosages and amounts of Oxycodone and Hydrocodone, to patients outside the usual course of his professional practice and without a legitimate medical purpose.

5. Defendant did so with the intent to prescribe Oxycodone and Hydrocodone outside the course of his professional practice and without a legitimate medical purpose.

6. All of the foregoing occurred in the State and Federal District of Nevada and elsewhere.

V. COLLATERAL USE OF FACTUAL ADMISSIONS

The facts set forth in Section IV of this Plea Agreement shall be admissible

against the Defendant under Fed. R. Evid. 801(d)(2)(A) at sentencing for any purpose. If the Defendant does not plead guilty or withdraws his guilty plea, the facts set forth in Section IV of this Plea Agreement shall be admissible at any proceeding, including a trial, for impeaching or rebutting any evidence, argument or representation offered by or on the Defendant's behalf. The Defendant expressly waives all rights under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410 regarding the use of the facts set forth in Section IV of this Plea Agreement.

VI. APPLICATION OF SENTENCING GUIDELINES PROVISIONS

A. Discretionary Nature of Sentencing Guidelines. The Defendant acknowledges that the Court must consider the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines") in determining the Defendant's sentence, but that the Sentencing Guidelines are advisory, not mandatory, and the Court has discretion to impose any reasonable sentence up to the maximum term of imprisonment permitted by statute.

B. Offense Level Calculations. The parties stipulate to the following calculation of the Defendant's offense level under the Sentencing Guidelines, acknowledge that these stipulations do not bind the Court, and agree that they will not seek to apply any other specific offense characteristics, enhancements or reductions:

The Defendant acknowledges that the statutory maximum sentence and any statutory minimum sentence limit the Court's discretion in determining the Defendant's sentence notwithstanding any applicable Sentencing Guidelines provisions.

Group 1: Count 1: 21 U.S.C. §§ 841(a)(1), (b)(1)(C)

Offense Level Calculation		USSG
Base Offense Level[1]	20	§ 2D1.1(c)(10)
Use of Special Skill	+2	§ 3B1.3
Adjusted Offense Level (Subtotal)	**22**	
Contingent Reduction for Acceptance of Responsibility	-2	§ 3E1.1(a)
Contingent Reduction for Government Motion for Acceptance of Responsibility	-1	§ 3E1.1(b)
Final Adjusted Offense Level	**19**	

C. Reduction of Offense Level for Acceptance of Responsibility. Under USSG § 3E1.1(a), the United States will recommend that the Defendant receive a two-level downward adjustment for acceptance of responsibility unless he (a) fails to truthfully admit facts establishing a factual basis for the guilty plea when he enters the plea; (b) fails to truthfully admit facts establishing the amount of restitution owed when he enters his guilty plea; (c) fails to truthfully admit facts establishing the forfeiture allegations when he enters his guilty plea; (d) provides false or misleading information to the United States, the Court, Pretrial Services, or the Probation Office; (e) denies involvement in the offense or provides conflicting statements regarding his involvement or falsely denies or frivolously contests conduct relevant to the offense; (f) attempts to withdraw his guilty plea; (g) commits or attempts to commit any crime; (h) fails to appear in court; or (i) violates the

[1] The Group 1 base offense level was calculated as follows: there were three prescriptions of Hydrocodone/Oxycodone for a total 10,800 milligrams of Hydrocodone/Oxycodone. This is equal to 72.36 kg of marijuana (10.8g x 6700g equals 72,360 grams). The parties stipulate to this calculation for purposes of sentencing only.

conditions of pretrial release.

Under USSG §3E1.1(b), if the Court determines that the Defendant's total offense level, before operation of § 3E1.1(a), is 16 or higher, and if the United States recommends a two-level downward adjustment pursuant to the preceding paragraph, the United States will move for an additional one-level downward adjustment for acceptance of responsibility before sentencing because the Defendant communicated his decision to plead guilty in a timely manner that enabled the United States to avoid preparing for trial and to efficiently allocate its resources.

D. Criminal History Category. The Defendant acknowledges that the Court may base his sentence in part on the Defendant's criminal record or criminal history. The Court will determine the Defendant's Criminal History Category under the Sentencing Guidelines.

E. Relevant Conduct. The Court may consider any counts dismissed under this Plea Agreement and all other relevant conduct, whether charged or uncharged, in determining the applicable Sentencing Guidelines range and whether to depart from that range.

F. Additional Sentencing Information. The stipulated Sentencing Guidelines calculations are based on information now known to the parties. The parties may provide additional information to the United States Probation Office and the Court regarding the nature, scope, and extent of the Defendant's criminal conduct and any aggravating or mitigating facts or circumstances. Good faith efforts to provide truthful information or to correct factual misstatements shall not be grounds for the Defendant to withdraw his guilty plea. The Defendant acknowledges

that the United States Probation Office may calculate the Sentencing Guidelines differently and may rely on additional information it obtains through its investigation. The Defendant also acknowledges that the Court may rely on this and other additional information as it calculates the Sentencing Guidelines range and makes other sentencing determinations, and the Court's reliance on such information shall not be grounds for the Defendant to withdraw his guilty plea.

VII. APPLICATION OF SENTENCING STATUTES

A. Maximum Penalty. The maximum penalty under 21 U.S.C. §§ 841(a) and 841(b)(1)(C) is 20 years imprisonment, a fine of $1,000,000, or both.

B. Factors Under 18 U.S.C. § 3553. The Court must consider the factors set forth in 18 U.S.C. § 3553(a) in determining the Defendant's sentence. However, the statutory maximum sentence and any statutory minimum sentence limit the Court's discretion in determining the Defendant's sentence.

C. Parole Abolished. The Defendant acknowledges that his prison sentence cannot be shortened by early release on parole because parole has been abolished.

D. Supervised Release. In addition to imprisonment and a fine, the Defendant will be subject to a three-year term of supervised release. Supervised release is a period of time after release from prison during which the Defendant will be subject to various restrictions and requirements. If the Defendant violates any condition of supervised release, the Court may order the Defendant's return to prison for all or part of the term of supervised release, which could result in the Defendant serving a total term of imprisonment equal to the statutory maximum prison

sentence of 20 years imprisonment.

E. Special Assessment. The Defendant will pay a $100.00 special assessment per count at the time of sentencing.

VIII. POSITIONS REGARDING SENTENCE

The Government will recommend that the Court sentence the Defendant to a sentence within the Sentencing Guidelines range as determined by the Court. Notwithstanding its agreement to recommend that the Defendant be sentenced as described in this Plea Agreement, the United States reserves its right to defend any lawfully imposed sentence on appeal or in any post-conviction litigation.

The Defendant may seek a downward adjustment pursuant to 18 U.S.C. § 3553, including probation, from any sentence the Court may impose.

The Defendant acknowledges that the Court does not have to follow these recommendations.

IX. RESTITUTION

In exchange for benefits received under this Plea Agreement, the Defendant agrees to make full restitution in an amount to be determined by the Court for all of the losses the Defendant caused by his schemes or offenses, whether charged or uncharged, pleaded to or not, and by all of his relevant conduct. 18 U.S.C. § 3663(a)(3).

X. FINANCIAL INFORMATION AND DISPOSITION OF ASSETS

Before or after sentencing, upon request by the Court, the United States, or the Probation Office, the Defendant will provide accurate and complete financial information, submit sworn statements, and/or give depositions under oath

concerning his assets and his ability to pay. The Defendant will surrender assets he obtained directly or indirectly as a result of his crimes, and will release funds and property under his control in order to pay any fine, forfeiture, or restitution ordered by the Court.

XI. THE DEFENDANT'S ACKNOWLEDGMENTS AND WAIVERS

A. Plea Agreement and Decision to Plead Guilty. The Defendant acknowledges that:

(1) He has read this Plea Agreement and understands its terms and conditions;

(2) He has had adequate time to discuss this case, the evidence, and this Plea Agreement with his attorney;

(3) He has discussed the terms of this Plea Agreement with his attorney;

(4) The representations contained in this Plea Agreement are true and correct, including the facts set forth in Section IV; and

(5) He was not under the influence of any alcohol, drug, or medicine that would impair his ability to understand the Agreement when he considered signing this Plea Agreement and when he signed it.

The Defendant understands that he alone decides whether to plead guilty or go to trial, and acknowledges that he has decided to enter his guilty plea knowing of the charges brought against him, his possible defenses, and the benefits and possible detriments of proceeding to trial. The Defendant also acknowledges that he decided to plead guilty voluntarily and that no one coerced or threatened his to enter into

this Plea Agreement.

B. Waiver of Appeal and Post-Conviction Proceedings. The Defendant knowingly and expressly waives: (a) the right to appeal any sentence imposed within or below the applicable Sentencing Guideline range as determined by the Court; (b) the right to appeal the manner in which the Court determined that sentence on the grounds set forth in 18 U.S.C. § 3742; and (c) the right to appeal any other aspect of the conviction or sentence and any order of restitution or forfeiture.

The Defendant also knowingly and expressly waives all collateral challenges, including any claims under 28 U.S.C. § 2255, to his conviction, sentence, and the procedure by which the Court adjudicated guilt and imposed sentence, except non-waivable claims of ineffective assistance of counsel.

The Defendant reserves only the right to appeal any portion of the sentence that is an upward departure or an upward variance from the Sentencing Guidelines range determined by the Court.

The Defendant acknowledges that the United States is not obligated or required to preserve any evidence obtained in the investigation of this case.

C. Removal / Deportation Consequences. The Defendant understands and acknowledges that if he is not a United States citizen, then it is highly probable that he will be permanently removed (deported) from the United States as a consequence of pleading guilty under the terms of this Plea Agreement. The Defendant has also been advised if his conviction is for an offense described in 8 U.S.C. § 1101(a)(43), he will be deported and removed from the United States and will not be allowed to return to the United States at any time in the future. The Defendant desires to plead

guilty regardless of any immigration consequences that may result from his guilty plea, even if the consequence is automatic removal from the United States with no possibility of returning. The Defendant acknowledges that he has specifically discussed these removal / deportation consequences with his attorney.

XII. ADDITIONAL ACKNOWLEDGMENTS

This Plea Agreement resulted from an arms-length negotiation in which both parties bargained for and received valuable benefits in exchange for valuable concessions. It constitutes the entire agreement negotiated and agreed to by the parties. No promises, agreements or conditions other than those set forth in this agreement have been made or implied by the Defendant, the Defendant's attorney, or the United States, and no additional promises, agreements or conditions shall have any force or effect unless set forth in writing and signed by all parties or confirmed on the record before the Court.

DAYLE ELIESON,
United States Attorney

DATE 11/26/18

KILBY MACFADDEN
Assistant United States Attorney

DATE 11/26/18

LANCE MANINGO
Counsel for the Defendant

DATE 11/26/18

DEVENDRA I. PATEL, M.D.
Defendant

CERTIFICATE OF MAILING

I hereby certify that I am employed by Nevada State Board of Medical Examiners and that on the 11th day of December 2018 I served a filed copy of COMPLAINT, via USPS e-certified return receipt mail to the following:

Devendrakumar I. Patel
Northeastern Nevada Cardiology PC
674 N. Cedar St.
Elko, NV 89801

Dated this 11th day of December, 2018.

[redacted]

Dawn DeHaven Gordillo
Legal Assistant

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint	Case Nos. 18-29352-1
Against	18-29352-2
DEVENDRAKUMAR I. PATEL, M.D.,	18-29352-3
Respondent.	

FILED
SEP - 6 2019
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Aaron Bart Fricke, Esq., Deputy General Counsel for the Board and attorney for the IC, and Devendrakumar I. Patel, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Brent Vogel, Esq., of the law firm of Lewis Brisbois Bisgaard & Smith LLP, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. Background

1. Respondent is a medical doctor currently licensed in inactive status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act). His license was originally issued on July 23, 2004 (License No. 11068).

2. On February 1, 2018, in Case No. 18-29352-1, the IC filed a formal First Amended Complaint (Complaint One) charging Respondent with violating the Medical Practice Act. Specifically, Complaint One alleges one (1) violation of NRS 630.301(4), Malpractice (Count I). Also on February 1, 2018, in Case No. 18-29352-2, the IC filed a formal First Amended Complaint

[1] All agreements and admissions made by Respondent are solely for final disposition of these matters and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

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Reno, Nevada 89521
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(Complaint Two) charging Respondent with violating the Medical Practice Act. Specifically, Complaint Two alleges one (1) violation of NRS 630.301(4), Malpractice (Count I), one (1) violation of NRS 630.301(7), Violating Patient's Trust for Financial Gain (Count II), and one (1) violation of NRS 630.301(8), Failure to Offer Appropriate Procedures for Financial Benefit (Count III). On December 11, 2018, in Case No. 18-29352-3, the IC filed a formal Complaint (Complaint Three) charging Respondent with violating the Medical Practice Act. Specifically, Complaint Three alleges one (1) violation of NRS 630.306(1)(c), Illegal Dispensing of Controlled Substances (Count I), one (1) violation of NRS 630.306(1)(p), Unsafe or Unprofessional Conduct (Count II), and one (1) violation of NRS 630.301(9), Disreputable Conduct (Count III). Complaints One, Two and Three are hereinafter referred to collectively as the "Complaints."

3. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of the Complaints, has reviewed and understands the Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaints.

5. Respondent is hereby advised of his rights regarding these administrative matters, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in these administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of

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administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. Terms & Conditions

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. Jurisdiction. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. Representation by Counsel/Knowing, Willing and Intelligent Agreement. Respondent acknowledges he is represented by counsel, and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. Waiver of Rights. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with these administrative matters. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him

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or that may apply to him in connection with the administrative proceedings resulting from the Complaints filed in this matter, including defense of the Complaints, adjudication of the allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. Acknowledgement of Reasonable Basis to Proceed. As of the time of entering into this Settlement Agreement, the allegations of the Complaints remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges that Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts that if these matters were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. Consent to Entry of Order. In order to resolve this Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I of Complaint Three, violation of NRS 630.306(1)(c), Illegal Dispensing of Controlled Substances.

b. Respondent's license shall be immediately revoked. Pursuant to NRS 622A.410(1), Respondent may not apply for reinstatement of his medical license for a period of three (3) years from the date of the Board's acceptance of this Agreement as an Order of the Board.

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c. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matters, which imposition of costs and expenses shall be effective upon the Board's acceptance, adoption and approval of this Agreement, the current amount being $10,103.88, not including any costs that may be necessary to finalize this Agreement. This Board order for the payment of costs shall be immediately stayed, until which time as Respondent reapplies for licensure, at which time, Respondent is ordered to pay the aforementioned costs and fees within sixty (60) days.

d. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

e. Respondent shall receive a Public Letter of Reprimand.

f. The remaining counts of the Complaints, and any other claims arising therefrom, shall be dismissed with prejudice.

6. Release From Liability. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. Procedure for Adoption of Agreement. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of the Complaints. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the

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adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. Effect of Acceptance of Agreement by Board. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the cases shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. Effect of Rejection of Agreement by Board. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering the Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. Binding Effect. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. Forum Selection Clause. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the parties consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

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12. Attorneys' Fees and Costs. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. Failure to Comply With Terms. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order To Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

Dated this 10 day of July, 2019.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [redacted]
Aaron Bart Hicke, Esq., Deputy General Counsel
Attorney for the Investigative Committee

Dated this 2 day of July, 2019.

Lewis Brisbois Bisgaard & Smith LLP

By: [redacted]
Brent Vogel, Esq.
Attorneys for Respondent

Dated this ____ day of _____, 2019.

Devendrakumar I. Patel, M.D., Respondent

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to any civil and administrative collection efforts available.

Dated this ____ day of _____, 2019.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
Aaron Bart Fricke, Esq., Deputy General Counsel
Attorney for the Investigative Committee

Dated this ____ day of _____, 2019.

Lewis Brisbois Bisgaard & Smith LLP

By: _____
Brent Vogel, Esq.
Attorneys for Respondent

Dated this ____ day of _____, 2019.

_____
Devendrakumar I. Patel, M.D., Respondent

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(775) 688-2559

07/02/2019 11:20AM 7757737338 ELKO FAMILY DENT STY PAGE 01/01

IT IS HEREBY ORDERED that the foregoing Settlement Agreement (Case Numbers 18-29352-1, 18-29352-2, 18-29352-3) is approved and accepted by the Nevada State Board of Medical Examiners on the 6th day of September 2019, with the final total amount of costs due of $10,103.88.

[redacted]

Rachakonda D. Prabhu, M.D., President
NEVADA STATE BOARD OF MEDICAL EXAMINERS

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Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/6/17	5/7/19	NV	Elko	Elko

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
3:17-CR-0114-LRH-VPC	United States District Court, District of Nevada

Reason/Charge
Distribute a Controlled Substance and Health Care Fraud; pleaded guilty to one count Distribute a Controlled Substance

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Devendra I. Patel, M.D.	

Name of Business/Industry/Entity

Provide explanation below:

I was indicted on December 6, 2017, in the United States District Court, District of Nevada on thirty-six counts of "Distribute a Controlled Substance" a violation of 21 USC § 841(a)(1), and three counts of Health Care Fraud, a violation of 18 USC § 1347(case no. 3:17-CR-0114_LRH-VPC). The charges related to the care and treatment of cardiac patients; I was alleged to have prescribed controlled substances for reasons other than legitimate medical purposes. I ultimately pleaded guilty to one count of Distribute a Controlled Substance and a conviction was entered on May 7, 2019. I was sentenced to thirty-seven months in the Federal Bureau of Prisons followed by thirty-six months of supervised release. I complied with all terms of my supervised release and was released from probation early.

Copies of the Indictment and Judgment are attached.

D. Patel

Original Signature (electronic, copies or stamps not accepted)

2/17/2025

Date

STEVEN W. MYHRE
Acting United States Attorney
District of Nevada
KILBY MACFADDEN
SUE P. FAHAMI
Nevada Bar Number 5634
Assistant United States Attorneys
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sue.p.fahami@usdoj.gov

Representing the United States of America

✓ FILED ____ RECEIVED
____ ENTERED ____ SERVED ON
COUNSEL/PARTIES OF RECORD

DEC - 6 2017

CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: _____ DEPUTY

SEALED

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

3:17-CR-0114-LRH-VPC

UNITED STATES OF AMERICA,

Plaintiff,

v.

DEVENDRA I. PATEL M.D.,
a.k.a., DEVENDRAKUMAR I. PATEL M.D.,

Defendant.

INDICTMENT FOR VIOLATION OF:

21 U.S.C. § 841(a)(1) - Distribute a Controlled Substance (Counts 1 through 36); and
18 U.S.C. § 1347 – Health Care Fraud (Counts 37 through 39)

UNDER SEAL

THE GRAND JURY CHARGES THAT:

At times material to this Indictment:

Introduction

1. The Defendant, Devendra I. Patel, M.D., ("Patel") is a licensed physician, with Nevada license number 11068, who has practiced medicine in Nevada since 2004. Defendant Patel previously practiced medicine in New York and Nebraska. He maintains his medical practice, Northeastern Nevada Cardiology, which is located at 674 North Cedar Street, Elko, Nevada. Defendant Patel is a cardiologist. As part of his practice, he prescribes Controlled Substances, including opioids, with a DEA license number BP6740662.

2. Under the Controlled Substances Act, Title 21, United States Code, Section 841(a) et seq., and Title 21, Code of Federal Regulations, Section 1306.04, a prescription for a controlled substance is not legal or effective unless it was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

3. Defendant Patel routinely prescribes various Schedule II-IV controlled substances including Fentanyl, Hydrocodone and Oxycodone for his patients, outside the usual course of professional practice, without a legitimate medical purpose.

4. Further, Defendant Patel routinely has his patients submit to unnecessary heart testing in order to fraudulently obtain private insurance, Medicare and Medicaid payments.

5. One such procedure he routinely administers, without medical necessity, is a nuclear stress test. A nuclear stress test, which involves injecting a radioactive dye into the patient's bloodstream, is typically ordered if you have undiagnosed heart problems or a diagnosis such as coronary artery disease. This test measures blood flow. The test provides images that can show areas of low blood flow through the heart and damaged heart muscle. The test usually involves taking two sets of images of your heart — one while at rest and another after the heart is stressed, either by exercise or medication.

6. Defendant Patel broadly performed EKGs on his patients. These tests routinely showed the results as abnormal. Patel performed the EKGs so that he could then order these nuclear stress tests for his patients, all without medical necessity. He utilized a poorly calibrated machine and presented his patients with fraudulent X-Rays, in order to deceive his patients into thinking they had coronary issues that needed to be treated by him.

7. Defendant Patel also would bill Medicare or Medicaid for these nuclear stress tests, when he did not actually perform the test on the patients.

8. Medicare and Medicaid continued paying for the unnecessary tests for Patel's patients, or paying for these tests that were not performed, resulting in Patel receiving fraudulent provider payments.

COUNTS ONE THROUGH TWENTY-ONE
(Distribution of Controlled Substances - Schedule II)

The Grand Jury incorporates Paragraphs One through Eight as though fully set forth herein.

On or about the dates set forth below, in the State and Federal District of Nevada,

DEVENDRA I. PATEL,

Defendant herein, did knowingly and intentionally distribute, a mixture and substance containing a detectable amount of a Schedule II controlled substance, as listed below, without a legitimate medical purpose and outside the usual course of professional practice, each of which constitutes a separate count of this Indictment:

Count	Approximate Date of Distribution	Patient	Controlled Substance
1	September 14, 2015	Patient A	Oxycodone
2	November 12, 2015	Patient A	Oxycodone
3	December 14, 2015	Patient A	Oxycodone
4	January 13, 2016	Patient A	Oxycodone
5	February 12, 2016	Patient A	Oxycodone
6	May 1, 2014	Patient B	Oxycodone
7	May 1, 2014	Patient B	Morphine Sulfate
8	May 30, 2014	Patient B	Oxycodone
9	May 30, 2014	Patient B	Morphine Sulfate
10	June 27, 2014	Patient B	Oxycodone
11	June 27, 2014	Patient B	Morphine Sulfate

12	July 25, 2014	Patient B	Oxycodone
13	July 25, 2014	Patient B	Morphine Sulfate
14	August 22, 2014	Patient B	Oxycodone
15	August 22, 2014	Patient B	Morphine Sulfate
16	September 20, 2014	Patient B	Oxycodone
17	September 20, 2014	Patient B	Morphine Sulfate
18	October 20, 2014	Patient B	Oxycodone
19	October 20, 2014	Patient B	Morphine Sulfate
20	November 20, 2014	Patient B	Oxycodone
21	November 20, 2014	Patient B	Morphine Sulfate

All in violation of Title 21, United States Code, Sections 841(a)(1), and Title 21, Code of Federal Regulations, Section 1306.04.

COUNTS TWENTY-TWO THROUGH TWENTY-FIVE
(Distribution of Controlled Substances - Schedule III)

The Grand Jury incorporates Paragraphs One through Eight as though fully set forth herein.

On or about the dates set forth below, in the State and Federal District of Nevada,

DEVENDRA I. PATEL,

Defendant herein, did knowingly and intentionally distribute, a mixture and substance containing a detectable amount of a Schedule III controlled substance, as listed below, without a legitimate medical purpose and outside the usual course of professional practice, each of which constitutes a separate count of this Indictment:

Count	Approximate Date of Distribution	Patient	Controlled Substance
22	November 22, 2015	Patient C	Hydrocodone-Acetaminophen aka "Norco"
23	December 20, 2015	Patient C	Hydrocodone-Acetaminophen aka "Norco"
24	January 19, 2016	Patient C	Hydrocodone-Acetaminophen aka "Norco"
25	February 15, 2016	Patient C	Hydrocodone-Acetaminophen aka "Norco"

All in violation of Title 21, United States Code, Sections 841(a)(1) and Title 21, Code of Federal Regulations, Section 1306.04.

COUNTS TWENTY-SIX THROUGH THIRTY-SIX
(*Distribution of Controlled Substances - Schedule IV*)

The Grand Jury incorporates Paragraphs One through Eight as though fully set forth herein.

On or about the dates set forth below, in the State and Federal District of Nevada,

DEVENDRA I. PATEL,

Defendant herein, did knowingly and intentionally distribute, a mixture and substance containing a detectable amount of a Schedule IV controlled substance, as listed below, without a legitimate medical purpose and outside the usual course of professional practice, each of which constitutes a separate count of this Indictment:

Count	Approximate Date of Distribution	Patient	Controlled Substance
26	August 22, 2017	Patient D	Xanax
27	August 22, 2017	Patient D	Ambien

28	August 22, 2017	Patient D	Provigil
29	September 28, 2017	Patient D	Xanax
30	September 28, 2017	Patient D	Ambien
31	September 28, 2017	Patient D	Provigil
32	September 28, 2017	Patient D	Tramadol
33	September 28, 2017	Patient D	Nuvigil
34	September 29, 2017	Patient E	Tramadol
35	September 29, 2017	Patient E	Nuvigil
36	September 29, 2017	Patient E	Ambien

All in violation of Title 21, United States Code, Sections 841(a)(1); and Title 21, Code of Federal Regulations, Section 1306.04.

COUNTS THIRTY-SEVEN THROUGH THIRTY-NINE
(Health Care Fraud)

The Grand Jury incorporates Paragraphs One through Eight as though fully set forth herein.

On or about June 19, 2014, continuing to on or about June 10, 2016, in the State and Federal District of Nevada,

DEVENDRA I. PATEL

did knowingly and willfully execute a scheme and artifice to defraud a health care benefit program, to wit: the Medicaid and Medicare Part B and D programs, and to obtain by means of materially false and fraudulent pretenses, representations, promises, and omissions, money and property owned by and under the custody and control of Medicaid and Medicare, in connection with the delivery of and payment for health care benefits, items and services, to wit: nuclear

stress tests, with each Patient, identified herein as Patients F, G and H, constituting a separate violation of Title 18, United States Code, Section 1347.

COUNT	Patient	Approximate Dates	Health Care Benefit
37	Patient F	June 19, 2015	Medicaid
38	Patient G	June 10, 2016	Medicaid
39	Patient H	June 19, 2014	Medicare Part B

DATED: this 6th day of December, 2017.

A TRUE BILL:

/S/

FOREPERSON OF THE GRAND JURY

STEVEN W. MYHRE
Acting United States Attorney

[redacted]

KILBY MACFADDEN
SUE P. FAHAMI
Assistant United States Attorneys

AO 245B (Rev. 02/18) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA v. DEVENDRA I. PATEL M.D.	**JUDGMENT IN A CRIMINAL CASE** Case Number: 3:17-cr-0114-LRH-CBC USM Number: 54504-048 Lance Maningo, Esq. Defendant's Attorney

THE DEFENDANT:

X pleaded guilty to count(s) Count 1 of the Indictment filed 12/6/17

☐ pleaded nolo contendere to count(s) _____
which was accepted by the court.

☐ was found guilty on count(s) _____
after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
21 U.S.C. § 841(a)(1)	Distribute a Controlled Substance	9/14/15	1

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s) _____

X Counts 2 through 39 are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

May 7, 2019
Date of Imposition of Judgment

[redacted]
Signature of Judge

Larry R. Hicks, United States District Judge
Name and Title of Judge

5/9/19
Date

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of: **THIRTY-SEVEN (37) MONTHS**

X The court makes the following recommendations to the Bureau of Prisons:
As Close as Possible to RENO, NV and RDAP

☐ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on

☐ as notified by the United States Marshal.

X The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

X before 2 p.m. on **August 6, 2019**.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to a _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

_____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of: **THREE (3) YEARS**

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court, not to exceed 104 tests annually.
   - X The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☐ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(check if applicable)*
5. X You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)*
6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. ç 20901, *et seq.*) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, or are a student, or were convicted of a qualifying offense. *(check if applicable)*
1. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

2. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.
3. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
4. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
5. You must answer truthfully the questions asked by your probation officer.
6. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
7. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
8. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
9. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
10. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
11. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchukus or tasers).
12. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
13. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.
14. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office User Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's signature_____ Date_____

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

SPECIAL CONDITIONS OF SUPERVISION

1. **Employment Restriction** – You must not engage in an occupation, business, or profession, or volunteer activity that would require or enable you to work in the medical profession unless directly supervised by a licensed physician who is willing to supervise the defendant. You are further prohibited from working or engaging in any business or activities involving the prescribing of opioid medication.

2. **Search and Seizure** - You shall submit to the search of your person, property, residence, or automobile under your control by the probation officer or any other authorized person under the immediate and personal supervision of the probation officer, without a search warrant to ensure compliance with all conditions of release.

3. **Access to Financial Information** - You must provide the probation officer access to any requested financial information and authorize the release of any financial information. The probation office will share financial information with the U.S. Attorney's Office.

4. **Debt Obligations** - You must not incur new credit charges, or open additional lines of credit without the approval of the probation officer.

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	JVTA Assessment*	Fine	Restitution
TOTALS	$100	N/A	$500,000	$N/A

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. ç 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss**	Restitution Ordered	Priority or Percentage
Clerk of Court Attention: Finance Case No.: 3:01-cr-124-LRH-WGC 333 Las Vegas Blvd. South, Room 1334 Las Vegas, Nevada 89101			
TOTALS		$_____	$ _____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. ç 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. ç 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: Devendra I. Patel M.D.
CASE NUMBER: 3:17-cr-114-LRH-CBC

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A X Lump sum payment of **$500,100** due immediately, balance due

☐ not later than _____, or
☐ in accordance with ☐ C, ☐ D, ☐ E, or ☐ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☐ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Defendant and Co-Defendant Names and Case Numbers *(including defendant number)*, Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☐ The defendant shall forfeit the defendant's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) JVTA assessment, (8) penalties, and (9) costs, including cost of prosecution and court costs.

Devendrakumar Ishwarbhai PATEL

License Number:
26987

License Type:
Medical Doctor

License Status:
Active-Conditions

Initial License Date:
Jan-09-2025

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Spring Creek

Public State:
Nevada

Public ZIP Code:
[redacted]

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Cardiovascular Diseases
Internal Medicine
Cardiovascular Diseases
Internal Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Medical College M.S. University / Baroda, India	Medical Doctor Degree	N/A	Dec-01-1981
Government Medical College, Vadodara University	Medical Doctor Degree	Jun-15-1977	Jan-31-1983

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Catholic Medical Center (Brooklyn Queens)	Internship/Residency	Internal Medicine	Jul-01-1989	Jun-30-1992
Catholic Medical Center / Jamaica, NY	Residency	Internal Medicine	Jul-01-1989	Jun-30-1992
St. Luke's Roosevelt Medical Center	Fellowship	Cardiology, Nuclear	Jul-01-1992	Jun-30-1994
St. Luke's Rosevelt Hospital / Amsterdam, NY	Fellowship	Cardiovasc Diseases	Jul-01-1992	Jun-30-1994
Interfaith Medical Center	Fellowship	Cardiovascular Diseases	Jul-01-1994	Jun-30-1996
Interfaith Medical Center / Brooklyn, NY	Fellowship	Cardiovasc Diseases	Jul-01-1994	Jun-30-1996

Board Actions

Summary Attachments

None.

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary Attachments

None.

Malpractice Information

Summary Attachments

PROFESSIONAL LIABILITY CLAIM, SETTLEMENT OR JUDGEMENT OF $5,000 OR MORE:

Date received by the Board: 5/3/2016
Reported by: Medicus Ins.
Date of act/omission: 10/2/2012
Details: Alleged delayed diagnosis of an MI resulting in unknown damage to a 58 year old male patient Settlement amount: $125,000 N/A
Court Case Number:CV-C-13-516
Total pages: 0

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12

12A

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

B30746

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Jorge Middle: Roberto Last: Menjivar

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: [redacted]

Telephone: [redacted] Email: [redacted]

APRN License #: 865069 Specialty: Family Across the Lifespan

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: CITY OF LAS VEGAS DETENTION CENTER

Practice Address: 3300 STEWART AVENUE Suite #:

City: LAS VEGAS State: NV Zip: 89101

Telephone: 702-385-1418 Fax: 803-878-8099 Email: [redacted]

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

PMP

[redacted]

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		n/a

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/31/2013	09/23/2014	AL	Carrollton	Pickens

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
201400000100	

Reason/Charge
DUI: Under Inf of Alc

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
State of Alabama V. Menjivar, Jorge Roberto	

Name of Business/Industry/Entity

Provide explanation below:

DUI 12/31/2013 AL, dismissed, pre-trial diversion;
The information that follows is the sequence of events that occurred on 12/31/2013 in Pickens County of Carrollton, AL. The evening of 30DEC2013 and the morning of 31DEC2013, I consumed alcoholic beverages while reunited with former in-laws in Alabama. It was late afternoon on 31 December 2013, and after eating and sleeping, I left their house and began driving to a store to pick-up some items. Having driven approximately 1.5 miles down the road, I felt that I should not have been driving and attempted to turn around. The road condition was favorable, the weather clear with no traffic on a two-lane road with the sun about set. When I attempted to turn around using the shoulder of the road, I had not realized that the recent paving on the road helped create and obscure the steep shoulder. As I turned around, my front passenger side tire went onto the soft shoulder, and my automobile slid down that shoulder. The officer arrived and asked if I had drunk any alcohol, and I answered that I had the night before and the morning of. He asked if I would agree to have my B.A.C. tested, and I refused. Due to the refusal, I was ticketed, arrested, and then released the following morning. Consulted with legal, and a pre-trial diversion was completed, with fines paid, services/courses/class/testing completed satisfactorily per the court.
DUI 02/22/2019 GA, Guilty plea, fines, probation,community service, and classes/courses completed
DUI 11/04/2022 GA, Convicted, fines, probation,

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/13/2025

Date

Court O.R.I.	COURT RECORD	COURT CASE NUMBER
AL 054023J		2014 00000100 (YEAR / NUMBER)

DISTRICT COURT OF PICKENS COUNTY — TICKET NUMBER: V5989887

DEFENDANT'S NAME: **STATE OF ALABAMA V. MENJIVAR JORGE ROBERTO** — CHARGE: **DUI: UNDER INFLU ALC**

M D Y		REASON
CONTINUANCE 2ND	M D Y	REASON

UTC-6A MAILED	NEW COURT DATE	UTC-6B ISSUED	UTC-6B CLEARANCE
M D Y	M D Y	M D Y	M D Y

WARRANT ISSUED	BOND SET	WARRANT SERVED	WARRANT RECALLED
M D Y	CASH DEPOSITED	M D Y	M D Y

CONDITIONAL BOND FORFEITURE ORDER ISSUED	M D Y	BOND FORFEITURE ORDERED FINAL	M D Y

ATTORNEY FOR DEFENDANT — CHECK IF APPLICABLE: ☐ Defendant informed of right to counsel ☐ Voluntarily waived counsel ☐ Defendant found indigent, counsel appointed

PLEA OF DEFENDANT (CHECK ONE)

1 ☐ Guilty as charged 2 ☐ Guilty of 3 ☑ Not guilty

ADJUDICATION (CHECK ONE) 1 ☐ Guilty as charged 2 ☐ Not guilty

3 ☐ Guilty of: 4 ☐ Nol prossed 5 ☑ Dismissed

ORDERS OF THE COURT

FINE	COURT COST	TOTAL FINE AND COURT COST
$0.00	$0.00	

ADDITIONAL PENALTIES/FEES/COSTS

HEAD INJURY DUI	CRIMINAL HISTORY DUI	CRIME VICTIMS (DUI/RECKLESS DRIVING) MISDEMEANOR MINIMUM $25.00
$0.00	$0.00	$0.00

HOUSING AND MAINTENANCE	MEDICAL	ATTORNEY RECOUPMENT	RESTITUTION	PARTIAL PAYMENTS AUTH
$0.00		$0.00	$0.00	See Notes Below

☐ JAILED M D Y	DAYS ____ RELEASED ☐ M D Y	LOCATION

☐ SENTENCE SUSPENDED ☐ PROBATION ☐ COMMUNITY SERVICE

0 DAYS 0 MONTHS 0 DAYS 0 MONTHS 0 DAYS 0 MONTHS 0 Hours

☐ TRAFFIC SAFETY PROGRAM M D Y ☐ SUBSTANCE ABUSE EVALUATION ☐ COMPLETED COURT REVIEW PROGRAM M D Y

COURT ORDERED LICENSE SUSPENSION		LICENSE SUSPENDED TO COURT: M D Y	RECEIVED BY
0 DAYS 0 MONTHS	☐ CONSECUTIVE ☐ CONCURRENT		

CONFIDENTIAL: ☑ NO ☐ IF YES: ☐ JUVENILE ☐ YOUTHFUL OFFENDER

Motion of State

DISPOSITION DATE	SIGNATURE FROM JUDGE/MAGISTRATE
M D Y: 09 23 14	/s/ DAVID LANCE BAILEY
CASE APPEALED M D Y	APPEAL BOND / CIRCUIT COURT CASE NUMBER

ARRESTING AGENCY (TYPE OF ARREST) ☐ STATE ☐ COUNTY ☐ MUNICIPAL

CASH RECEIVED FROM NAME AND TITLE	RECEIPT #	AMOUNT	DATE M D Y
		$0.00	

LICENSE ATTACHED ☐ YES ☐ NO DPS RECEIVED LICENSE ☐ YES ☐ NO

COURT ACTION AND DISPOSITION

ELECTRONICALLY FILED
9/23/2014 1:36 PM
54-TR-2014-000001.00
CIRCUIT COURT OF
PICKENS COUNTY, ALABAMA
BOBBY W COWART, CLERK

IN THE DISTRICT COURT FOR PICKENS COUNTY, ALABAMA

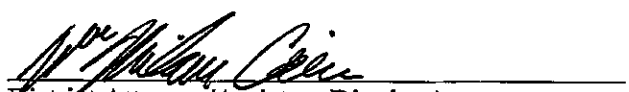
STATE OF ALABAMA,	}	
	}	
v.	}	**Case No. TR 14-1**
	}	
JORGE ROBERTO MENJIVAR,	}	
Defendant.	}	

MOTION TO DISMISS

COMES NOW the State of Alabama, by and through J. Chris McCool, District Attorney for the 24th Judicial Circuit, and requests entry of an Order dismissing the above-styled cause, as grounds therefore submits as follows:

1. That the Defendant entered into a Pre-Trial Diversion Agreement with the District Attorney's office.
2. The Defendant has completed all phases of Pre-Trial Diversion in this case.
3. That justice will best be served if the aforementioned case is dismissed.

WHEREFORE, the State of Alabama respectfully requests entry of an Order dismissing the above-styled cause.



District Attorney/Assistant District Attorney

ORDER

_____ GRANTED this the ____ day of _____, _____.

_____ DENIED this the ____ day of _____, _____.

_____

JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/22/2019	08/03/2020	GA	McDonough	Henry
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
19SR1718				
Reason/Charge				
DUI, DRIVING ON WRONG SIDE OF ROADWAY, AND OBSTRUCTION OF OFFICERS				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
State of Ga V. Menjivar, Jorge				
Name of Business/Industry/Entity				

Provide explanation below:

DUI 02/22/2019 GA, Guilty plea, fines, probation,community service, and classes/courses completed. The events that follow are what occurred on February 25, 2019 in Henry County of McDonough, GA, after an arrest for driving under the influence. The facts of that night, I consumed too much alcohol while having a reunion with friends, simultaneously dealing with underlying military traumas, previous job(s) traumas, and relationship problems that went unresolved. I recognized periods in my past where I felt depressed; however, a prior diagnosis from Veterans Affairs was never discovered or conveyed until uncovered after this event. On February 27, 2019, I called my provider, notifying her of my need to start an antidepressant and the events that prompted the call. A prescription for medication was ordered and picked up the next day. After the incident, my peers and I called Veterans Affairs to begin the substance abuse training program (SATP) in an intensive outpatient setting. During the eight mandatory weekly classes that started in March, we took various self-improvement, coping, and assertiveness classes. Along with the types, we had weekly drug/alcohol screens, in which I remained clean. After the mandatory courses, I stayed to complete the capstone portion of the program.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/13/2025

Date

ACCUSATION

IN THE STATE COURT OF HENRY COUNTY,
STATE OF GEORGIA
2019-ST-SR- 1718 .

APRIL TERM 2019

FILED IN OFFICE
STATE COURT
HENRY COUNTY, GA

MAY 02 2019

EP

MICHELLE B. GARDNER
CLERK OF STATE COURT HENRY COUNTY, GA

FOR

STATE OF GEORGIA

VS.

JORGE MENJIVAR

CT 1: DRIVING UNDER THE INFLUENCE OF ALCOHOL (DUI) (40-6-391(a)(1))
CT 2: DRIVING UNDER THE INFLUENCE (40-6-391(A)(5))
CT 3: DRIVING ON WRONG SIDE OF ROADWAY (40-6-40)
CT 4: OBSTRUCTION OF OFFICERS (16-10-24)

PAMELA M. BETTIS
SOLICITOR-GENERAL

GEORGIA, HENRY COUNTY
I certify that the foregoing is a true and exact copy of the original which appears of record in this office.
In witness whereof I have this 1st day of January 2021 affixed my seal and signature.

clk for

LYNNE M. POLICARO
CLERK OF STATE COURT HENRY COUNTY, GA

ACCUSATION

STATE OF GEORGIA, HENRY COUNTY

COUNT 1

On behalf of the people of the State of Georgia, the undersigned, as prosecuting attorney for the county and state aforesaid, does hereby charge and accuse JORGE MENJIVAR with the offense of **DRIVING UNDER THE INFLUENCE OF ALCOHOL (DUI) (40-6-391(a)(1))**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **February 25, 2019**, be in actual physical control of a moving vehicle while under the influence of alcohol to the extent that it was less safe for the said accused to drive, contrary to the laws of this state, the good order, peace and dignity thereof.

COUNT 2

The undersigned, as prosecuting attorney, does further charge and accuse JORGE MENJIVAR with the offense of **DRIVING UNDER THE INFLUENCE (40-6-391(A)(5))**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **February 25, 2019**, be in actual physical control of a moving vehicle while having an alcohol concentration of 0.08 grams or more at a time within three hours after such actual physical control, from alcohol consumed before such actual physical control ended, contrary to the laws of this state, the good order, peace and dignity thereof.

COUNT 3

The undersigned, as prosecuting attorney, does further charge and accuse JORGE MENJIVAR with the offense of **DRIVING ON WRONG SIDE OF ROADWAY (40-6-40)**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **February 25, 2019**, fail to drive a vehicle on the right half of the roadway on Hwy 81, a roadway of sufficient width in violation of Official Code of Georgia, Section 40-6-40, contrary to the laws of this state, the good order, peace and dignity thereof.

COUNT 4

The undersigned, as prosecuting attorney, does further charge and accuse JORGE MENJIVAR with the offense of **OBSTRUCTION OF OFFICERS (16-10-24)**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **February 25, 2019**, knowingly and willfully obstruct or hinder Officer Broadway and Officer Gatchel, law enforcement officers in the lawful discharge of their official duties by refusing to comply to the officer's lawful commands, contrary to the laws of this state, the good order, peace and dignity thereof.

[redacted]

ASSISTANT SOLICITOR GENERAL

Defendant: Jorge Menjivar Case Number: 19SR01718

The undersigned defendant waives formal arraignment, copy of the accusation, and list of witnesses and pleas as follows:
This the ____ day of _____, 20__

_____ Not Guilty to Count 1
_____ Not Guilty to Count 2
_____ Not Guilty to Count 3
_____ Not Guilty to Count 4
_____ Not Guilty to Count 5
_____ Not Guilty to Count 6

_____ _____
Defendant Assistant Solicitor General

_____
Attorney for the Defendant GA Bar Number

The defendant waives his rights to trial and enters a plea as follows:
This the 6 day of August, 20 19

~~x~~	~~Guilty~~	~~Nolo Contendere~~	~~to Count 1~~	JP
x	Guilty	Nolo Contendere	to Count 2	
x	Guilty	Nolo Contendere	to Count 3	
x	Guilty	Nolo Contendere	to Count 4	
_____	Guilty	Nolo Contendere	to Count 5	
_____	Guilty	Nolo Contendere	to Count 6	

FILED IN OPEN COURT
STATE COURT
HENRY COUNTY, GA
AUG 06 2019
MICHELE B. GARDNER
COURT, HENRY COUNTY

[redacted] _____
Defendant Assistant Solicitor General

[redacted]
Attorney for the Defendant GA Bar Number

We the jury find the Defendant: (circle the verdict)

Guilty Not Guilty to Count 1
Guilty Not Guilty to Count 2
Guilty Not Guilty to Count 3
Guilty Not Guilty to Count 4
Guilty Not Guilty to Count 5
Guilty Not Guilty to Count 6

_____
_____
This ____ day of _____, 20__

_____
Jury Foreperson

After Trial the Court finds (circle the verdict)

Guilty Not Guilty to Count 1
Guilty Not Guilty to Count 2
Guilty Not Guilty to Count 3
Guilty Not Guilty to Count 4
Guilty Not Guilty to Count 5
Guilty Not Guilty to Count 6

_____
_____
This ___ day of _____, 20__

_____
Judge, State Court of Henry County

IN THE STATE COURT OF HENRY COUNTY

STATE OF GEORGIA

STATE OF GEORGIA

vs.

FILED IN OPEN COURT
STATE COURT
HENRY COUNTY, GA
AUG 26 2019
FOR
MICHELE B. GARDNER
CLERK OF STATE COURT, HENRY COUNTY, GA

CASE NO.: 2019 STSR 17180

Jorge Menjivar
Defendant.

WAIVER AND RECORD OF REPRESENTED DEFENDANT PRIOR TO ENTERING A PLEA

I, the undersigned Defendant am not under the influence of alcohol or drugs. I am not suffering from any mental or physical disabilities which would prevent me from entering a plea to the charge(s) against me. I have read the citation/accusation. I understand I am charged with DUI, DUI Wrong Way + Obstructions I understand the law provides for a maximum sentence of twelve (12) months imprisonment which may or may not be served on probation and a fine up to $1,000.00 for each offense ($5,000.00 for misdemeanors of a high and aggravated nature). As a part of my sentence, I may be required to perform community service. I understand the minimum sentence which can be imposed on the present charge(s) is 12 months, $200 fine + 40 hrs 4 9th DUI. I am represented by council and have had sufficient time to discuss this case with my attorney and I am satisfied with my attorney's advice. I understand by entering a plea of guilty or nolo contendere I waive the following rights:

(1) The right to a speedy and public trial by jury;
(2) The right to have the State prove my guilt beyond a reasonable doubt;
(3) The right to use the presumption of innocence in my favor;
(4) The right to confront and cross examine witnesses against me;
(5) The right to subpoena witnesses to testify in my behalf;
(6) The right to testify myself and to offer other evidence; and
(7) The right not to incriminate, testify or produce evidence against myself.

I now desire to enter my plea of Guilty to the charge(s) against me. This plea is free and voluntary. I have not been told what sentence will be imposed. No promises or threats have been made to me by anyone to induce me to enter this plea. I understand the Judge is not bound by any negotiations or recommendations.

If placed on non-reporting or reporting probation, I cannot violate any criminal laws of any governmental unit or any special conditions of probation without being subject to revocation for the balance of my sentence. I understand the Court may make any sentence run consecutively, that is, one after the other.

If not a citizen of the United States my plea may result in deportation, the exclusion of admission to this country or denial of naturalization under Federal Law. There have been no promises made to me concerning my right to remain in the United States.

I understand by entering a plea to any crime of domestic violence, I will be prohibited from possessing, receiving, shipping and transporting a firearm and/or ammunition under Federal Law.

I hereby acknowledge/waive receipt of a copy of the citation/accusation in the above-styled case.

I have read and have had read to me the above and foregoing waiver. I understand it and have no questions regarding its contents.

I understand that under penalty of law, I am answering the following question truthfully:

Do you have a Georgia Weapons Carry Permit?
(Write the word "Yes" or "No" as is appropriate) Yes

[redacted] 8/6/2019
Defendant **Date**

I hereby certify to the Court, I have fully explained the above and foregoing waiver to the Defendant. In my opinion, the Defendant understands the contents of it and is entering this plea freely and voluntarily.

[redacted] 8/6/19
Attorney for Defendant **Date**

I am satisfied the Defendant's plea is being given freely, voluntarily and intelligently and he/she is competent and is able to understand the nature and consequences of his/her plea. The Court is further satisfied there has been a sufficient factual basis shown for the acceptance of this plea.

SO ORDERED, this 6th day of August, 2019

[redacted]
Pandora E. Palmer
Judge, Henry County State Court
McDonough, Georgia
Flint Judicial Circuit

STATE COURT OF HENRY COUNTY
SENTENCE AND PROBATION ORDER

FILED IN PAGE ONE COURT
STATE COURT
HENRY COUNTY, GA

STATE OF GEORGIA vs.

Menjivar Jorge
DEFENDANT

AUG 06 2019

SERVE WITH SUSPENSION Y/N

CASE NO. 19 (SR) / TR 1718 PEP

Disposition is made of the charges against Defendant as follows:

COUNT	OFFENSE 2/22/19	DISPOSITION (Plea/Found Guilty)	SENTENCE	FINE: Inclusive Of Surcharges
1	Driving under the influence of Alcohol (DUI)			
2	Driving under the influence	Guilty	12mos probation 24hrs jail	1000
3	Driving on wrong side road	Guilty		140
4	Obstruction of officers	Guilty	12mos prob conc. 1000 48hrs jail conc.	

IT IS HEREBY COMMANDED that the above DEFENDANT serve a sentence of 12 months, consisting of 2 days/weeks in jail and the remainder on Probation subject to the requirements and conditions of this Order as checked below and as shown on reverse.

- ✓ (1) Jail time ~~to be~~ served ~~instanter/in 48-hour increments weekly/ begin~~ by _____. Book/fingerprint/release by Credit for time served.
- ✓ (2) Probation period to begin ~~instanter~~/consecutive to _____. ~~No probation if paid by~~ _____.
- ___ (3) This sentence may be served on the Work Release Program subject to all rules attendant thereto.
- ___ (4) This sentence shall commence upon Defendant's release from his/her present incarceration and all incarceration following consecutively thereupon. As a term and condition of this sentence, Defendant shall notify probation of his/her release from incarceration within 48 hours thereof. This sentence shall not begin running until probation shall receive such notice from Defendant. Defendant's failure to notify probation of his/her release from incarceration shall be a violation of the conditions of this sentence authorizing revocation of this sentence of probation.
- ___ (5) Defendant shall serve _____ months of this sentence under ~~house~~ arrest with electronic monitoring (with alcohol sensor/ GPS).
- ✓ (6) Defendant shall report in person/ in writing no less than (Weekly / Monthly / Semi-Monthly / Quarterly) as directed by probation.
- ___ (7) In addition to the fine amounts provided above, and probation fees and costs provided in paragraph 10, below, Defendant shall pay the following amounts:

Court Costs	Attorney Fee/Restitution to Henry Co.	Victim/Other Restitution	Multiple Offender Photo	Contempt	Other:

- ✓ (8) Fines and court costs (but not probation fees or victim restitution) may be paid via community service in lieu of cash, credited at the rate of $10 per hour worked. Attorney fee restitution may/may not be paid via community service.
- ___ (9) Victim restitution is to be paid through probation to (give name only): _____.
- ✓ (10) In addition to all other amounts due hereunder, Defendant shall pay supervision fees, drug testing fees, electronic monitoring fees and other costs as directed by probation, as approved by the Court.
- ✓ (11) Defendant shall comply with the Court's General Conditions of probation (see opposite side).
- ✓ (12) Defendant shall perform 80 hours of community service work at a rate of 8 hours per week. Said work shall be performed in Henry County/county of residence. within 10days-show proof to P.O of cls Approved by Judge
- ✓ (13) Defendant shall not consume any alcoholic beverages, illegal drugs or narcotics nor be in the presence of anyone consuming alcohol, illegal drugs, narcotics or any other substances which may prove dangerous to oneself or others.
- ✓ (14) Within ___ days of the commencement of the probationary period, Defendant shall undergo an evaluation for: substance abuse / anger management / family violence / general mental health issues by a professional counselor which must include a drug screen, and shall sign whatever papers necessary to have reports sent to probation. Defendant shall supply the evaluator with a current copy of his/her criminal history and the incident report from this incident. The recommendations of the evaluator shall become a part of the probation requirements, and Defendant shall strictly comply therewith.
- ___ (15) Defendant shall attend a minimum of _____ **NA/AA/similar self-help 12-step program meetings each week for the duration of Probation.**
- ___ (16) **On each report to Probation, Defendant shall bring proof of attendance of AA meetings, counseling, and a written statement as to the consumption of drugs/alcoholic beverages during the probation period.**
- ✓ (17) At his/her own expense, Defendant shall attend:

___ Anger Management Counseling	___ Family Violence Counseling	___ Substance Abuse Program
✓ Defensive Driving School	✓ Risk Reduction School	___ DUI Court
___ Theft Offender Counseling	___ Victim Impact Panel	___ Other: _____

Said program(s) to be begun within 30 days of commencement of the probationary period and continuing until successful completion of the program(s). show to P.O proof completed not less than 2x month

Hearing DS stop sign

- ✓ (18) Defendant shall be subject to a drug/alcohol screen at the direction of a probation officer, at Defendant's expense.
- ✓ (19) Defendant shall submit to search of his/her person and property upon request by any probation supervisor or certified police officer.
- ___ (20) Defendant is to have no contact / no violent contact with _____.
- ___ (21) Defendant shall complete the requirements for obtaining a General Equivalency Diploma (G.E.D.).
- ___ (22) Probation will be non-reporting / terminated upon performance of all special conditions, with no violations, to serve a minimum of _____ months. **NOTE:** If items 18 and 19 are checked above, those conditions continue to apply to non-reporting probation.
- ___ (23) Defendant shall obtain / reinstate Georgia Driver's License by _____.
- ✓ (24) Other 11 months to pay weekly follow any treatment/anger meetings thro the program given at probation

SO ORDERED this 6th day of August 2019.

[redacted]
JUDGE, STATE COURT OF HENRY COUNTY

DECLARATION BY DEFENDANT: I have read or have had read to me the conditions of probation in this Order (including the Court's General Conditions of Probation on page two). I understand that my probation is an alternative to a jail sentence. I also understand my probation may be revoked and the balance of my probation served in jail if I fail to abi[redacted]

8/6/19
DATE

DEFENDANT

PROBATION/COURT SERVICES OFFICER

(Rev. 05/2016)

STATE OF GEORGIA

Vs

SUCCESSFUL TERMINATION

FILED IN OFFICE
STATE COURT
HENRY COUNTY, GA

AUG 05 2020

TSR FOR
LYNNE M. POLIDARO
CLERK OF STATE COURT, HENRY COUNTY, GA

Menjivar, Jorge
DEFENDANT

19SR1718
CASE NUMBER

D.U.I, Driving on Wrong side of the Road and Obstruction of Officers
OFFENSE

The above named defendant entered a plea of guilty in theState Court of Henry County, and was placed on probation by the Court's judgment and order dated the 6th day of August 2019, for the period of 12 months from said date.

It is recommended that the defendant's probation be TERMINATED for the following reasons:

As of 08/03/2020, the defendant has completed all terms and conditions of probation and has paid all Court fines and supervision fees in full.

I affirm that documentation to support the above request is in offender's file.

8-3-2020
Date

Trent Warren, Probation Officer

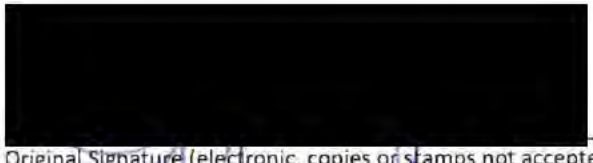
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/14/2022	11/02/2023	GA	McDonough	Henry
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2022-ST-SR-4113-SNK				
Reason/Charge				
Driving Under the Influence of the Alcohol to the Extent it is Less Safe for the Person to Drive, and Failure to Maintain Lane				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of Georgia vs. Jorge Roberto Menjivar				
Name of Business/Industry/Entity				

Provide explanation below:

On November 4, 2022, I was arrested for driving under the influence and failure to maintain lane. That evening, I knowingly consumed alcohol in a public location, where I had arranged for a designated driver—an unfamiliar associate of an acquaintance. En route to visit a friend in another city, we were involved in a single-car collision. Following the impact, the designated driver fled the scene. When law enforcement arrived, I reported the events and provided information about the designated driver, though no evidence of their existence was found. I cooperated with the authorities, submitting to both a breathalyzer and a field sobriety test (resulting in a reading over the legal limit and a failed test, respectively). I was subsequently arrested and released shortly thereafter, as the designated driver had not yet been located. Legal representation was secured, and a court date was scheduled. Around October 31, 2023, I was summoned for jury selection, and the trial took place from November 2, 2023. Surprisingly, I was found guilty by the jury, likely influenced by a prior 2019 DUI conviction and the absence of substantial evidence or witnesses. Although the possibility of an appeal was considered, the advice received highlighted the risk of serving the full sentence if the appeal was unsuccessful, despite potential early release for good behavior. Following the hearing, I was taken into custody, and on December 11, 2023, I was released early for good behavior with a sentence of 24 months, including 120 days in jail and the remainder on probation. Conditions include undergoing a substance abuse evaluation within 60 days of release, monthly probation officer meetings, payment of fines and court costs, compliance with court conditions, abstinence from alcohol and drugs, attendance at self-help 12-step/recovery meetings, property searches upon probation officer request, and mandatory alcohol/drug screenings with an interlock device installation. On December 19, 2023, I applied to the Georgia Nursing Association Peer Assistance Program, with the first urine and drug screening conducted on December 22, 2023. Program requirements included a scheduled clinical evaluation on 01/02/2024. My workplace director was informed of my incarceration on 11/03/2023, with periodic updates provided. On 12/11/2023, a meeting with both my director and vice-president fully disclosing the events, including the 2019 guilty plea for DUI. Due to the remote nature of my position, I was able to return to work on 12/12/2023. On April 16, 2024, a mental physical evaluation was completed, and I was found safe to practice. Affinity monitoring, random monthly drug screens, and psychotherapy with a board-certified psychiatrist in addiction medicine continue.



Original Signature (electronic, copies or stamps not accepted)

2/13/2025

Date

ACCUSATION

IN THE STATE COURT OF HENRY COUNTY,

STATE OF GEORGIA

2022-ST-SR- 4113

OCTOBER TERM 2022

STATE OF GEORGIA
VS.
JORGE ROBERTO MENJIVAR

CT 1: DRIVING UNDER THE INFLUENCE (40-6-391(A)(5))
CT 2: DRIVING UNDER THE INFLUENCE OF ALCOHOL (DUI) (40-6-391(a)(1))
CT 3: FAILURE TO MAINTAIN LANE (40-6-48)

FILED IN OFFICE
STATE CC
HENRY COUNTY GA
DEC 05 2022
LYNNE M.
CLERK OF STATE COURT

PAMELA M. BETTIS
SOLICITOR-GENERAL

GEORGIA, HENRY COUNTY
I certify that the foregoing is a true and exact copy of the original which appears of record in this office.
In witness whereof I have
this 19 day of December 20 24
affixed my seal and signature
Meredith Emondi for
LYNNE M. POLICARO
CLERK OF STATE COURT HENRY COUNTY, GA

ACCUSATION

STATE OF GEORGIA, HENRY COUNTY

COUNT 1

On behalf of the people of the State of Georgia, the undersigned, as prosecuting attorney for the county and state aforesaid, does hereby charge and accuse JORGE ROBERTO MENJIVAR with the offense of **DRIVING UNDER THE INFLUENCE (40-6-391(A)(5))**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **November 04, 2022**, be in actual physical control of a moving vehicle while having an alcohol concentration of 0.08 grams or more at a time within three hours after such actual physical control, from alcohol consumed before such actual physical control ended, contrary to the laws of this state, the good order, peace and dignity thereof.

COUNT 2

The undersigned, as prosecuting attorney, does further charge and accuse JORGE ROBERTO MENJIVAR with the offense of **DRIVING UNDER THE INFLUENCE OF ALCOHOL (DUI) (40-6-391(a)(1))**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **November 04, 2022**, be in actual physical control of a moving vehicle while under the influence of alcohol to the extent that it was less safe for the said accused to drive, contrary to the laws of this state, the good order, peace and dignity thereof.

COUNT 3

The undersigned, as prosecuting attorney, does further charge and accuse JORGE ROBERTO MENJIVAR with the offense of **FAILURE TO MAINTAIN LANE (40-6-48)**, for that the said accused, did in HENRY COUNTY, Georgia, on or about **November 04, 2022**, while operating a motor vehicle upon Honey Creek Drive, a roadway divided into clearly marked lanes for traffic, did unlawfully fail to drive his vehicle as nearly as practicable entirely within a single traffic lane without first ascertaining that such movement could be made with safety, contrary to the laws of this state, the good order, peace and dignity thereof.

Nedra Howard

ASSISTANT SOLICITOR GENERAL

STATE COURT OF HENRY COUNTY
SENTENCE AND PROBATION ORDER
PAGE ONE

STATE OF GEORGIA vs. Menjivar, Jorge Roberto
DEFENDANT

SERVE WITH SUSPENSION (Y) / N

CASE NO. 22 (SR) / TR 4113 (SNK)

Disposition is made of the charges against Defendant as follows:

COUNT	OFFENSE	DISPOSITION (Plea/Found guilty)	SENTENCE	FINE: Inclusive Of Surcharges
1.	Driving under the Influence	found guilty	12 months Probation 120 days jail	1000
2.	Driving under the influence of Alcohol (DUI)	found guilty	merged to Ct. 1	—
3.	failure to maintain lane	found guilty	12 months Probation consecutive	500

IT IS HEREBY COMMANDED that the above DEFENDANT serve a sentence of 24 months, consisting of 120 days/months in jail and the remainder on Probation subject to the requirements and conditions of this Order as checked below and as shown on reverse.

✓ (1) Jail time to be served instanter/in 48 hour increments weekly/ begun by _____ Book/fingerprint/release by: _____.
✓ (2) Probation period to begin instanter/consecutive to incarceration. No probation if paid by _____.
___ (3) This sentence may be served on the Work Release Program subject to all rules attendant thereto.
___ (4) This sentence shall commence upon Defendant's release from his/her present incarceration and all incarceration following consecutively thereupon. As a term and condition of this sentence, Defendant shall notify probation of his/her release from incarceration within 48 hours thereof. This sentence shall not begin running until probation shall receive such notice from Defendant. Defendant's failure to notify probation of his/her release from incarceration shall be a violation of the conditions of this sentence authorizing revocation of this sentence of probation.
✓ (5) Defendant shall serve _____ months of this sentence under house arrest with electronic monitoring (with alcohol sensor/ GPS).
✓ (6) Defendant shall report in person/ remotely no less than (Waekly / Monthly / Semi-Monthly / Quarterly) as directed by probation.
✓ (7) In addition to the fine amounts provided above, and probation fees and costs provided in paragraph 10, below, Defendant shall pay the following amounts:

Court Costs	Attorney Fee/Restitution to Henry Co.	Victim/Other Restitution	Multiple Offender Photo	Contempt	Other:
175					

✓ (8) Fines and court costs (but not probation fees or victim restitution) may be paid via community service in lieu of cash, credited at the rate of $10 per hour worked. Attorney fee restitution may/may not be paid via community service.
___ (9) Victim restitution is to be paid through probation to (give name only): _____.
✓ (10) In addition to all other amounts due hereunder, Defendant shall pay supervision fees, drug testing fees, electronic monitoring fees and other costs as directed by probation, as approved by the Court.
✓ (11) Defendant shall comply with the Court's General Conditions of probation (see opposite side).
✓ (12) Defendant shall perform _____ hours of community service work at a rate of _____ hours per week. Said work shall be performed in Henry County/county of residence.
✓ (13) Defendant shall not consume or possess any alcoholic beverages, illegal drugs or narcotics nor be in the presence of anyone consuming alcohol, illegal drugs, narcotics or any other substances which may prove dangerous to oneself or others.
✓ (14) Within 60 days of the commencement of the probationary period, Defendant shall undergo an evaluation for: substance abuse / anger management / family violence / general mental health issues by a professional counselor which must include a drug screen, and shall sign any releases necessary to have reports sent to probation. Defendant shall supply the evaluator with a current copy of his/her criminal history and the incident report from this incident. The recommendations of the evaluator shall become a part of the probation requirements, and Defendant shall strictly comply therewith.
of release
✓ (15) Defendant shall attend a minimum of 2 NA/AA/similar self-help 12-step program meetings each week for the duration of Probation.
___ (16) On each report to Probation, Defendant shall bring proof of attendance of AA meetings, counseling, and a written statement as to the consumption of drugs/alcoholic beverages during the probation period.
✓ (17) At his/her own expense, Defendant shall attend:
___ Anger Management Counseling ___ Family Violence Counseling ___ Substance Abuse Program ___ FOR
___ Defensive Driving School ✓ Risk Reduction School ___ DUI Court
___ Theft Offender Counseling ___ Victim Impact Panel ___ Other _____
Said program(s) to be begun within 30 days of commencement of the probationary period and continuing until successful completion of the program(s).
of release
✓ (18) Defendant shall be subject to a drug/alcohol screen at the direction of a probation officer, at Defendant's expense.
✓ (19) Defendant shall submit to search of his/her person and property upon request by any probation supervisor or certified police officer.
___ (20) Defendant is to have no contact / no violent contact with _____.
___ (21) Defendant shall complete the requirements for obtaining a General Equivalency Diploma (G.E.D.).
___ (22) Probation will be non-reporting / terminated upon performance of all special conditions, with no violations, to serve a minimum of _____ months. NOTE: If items 18-20 are checked above, those conditions continue to apply to non-reporting probation.
___ (23) Defendant shall obtain / reinstate Georgia Driver's License by _____.
✓ (24) Other must install interlock device

FILED IN OPEN COURT
STATE COURT
HENRY COUNTY, GA
NOV 02 2023
LYNNE M. POLICARD
CLERK OF STATE COURT, HENRY COUNTY, GA

SO ORDERED this 2nd day of November 2023.

JUDGE, STATE COURT OF HENRY COUNTY

DECLARATION BY DEFENDANT: I have read or have had read to me the conditions of probation in this Order (including the Court's General Conditions of Probation on page two). I understand that my probation is an alternative to a jail sentence. I also understand my probation may be revoked and the balance of my probation served in jail if I fail to abide by the conditions of this sentence.

11/2/23
DATE

DEFENDANT

LBanks
PROBATION/COURT SERVICES OFFICER

(Rev. 8/21)

IN THE STATE COURT OF HENRY COUNTY
STATE OF GEORGIA
PAGE TWO

IN RE: General Conditions of Probation

ORDER

A. The following general conditions of probation shall apply in each sentence on each case in which the Court places a Defendant on probation:

(1) do not violate the criminal laws of any government unit;
(2) avoid injurious and vicious habits - including alcohol intoxication and use of narcotics and other dangerous drugs unless lawfully prescribed;
(3) avoid persons or places of disreputable or harmful character;
(4) report to the probation supervisor as directed and permit such supervisor to visit Defendant at home or elsewhere;
(5) work faithfully at suitable employment insofar as may be possible;
(6) do not change place of abode, move outside the jurisdiction of the Court or leave the state for any period of time without prior permission of the probation supervisor;
(7) support Defendant's legal dependent(s) to the best of Defendant's ability; and,
(8) if permitted to move or travel to another state, agree to waive extradition from any jurisdiction where he/she may be found and not contest any effort by any jurisdiction to return him/her to this state.

B. The Defendant shall pay any fine, restitution, costs, probation supervision fees, or any other sum of money lawfully imposed by this Court or by law as and when instructed by his/her probation supervising officer, and shall pay for any counseling and/or treatment ordered by the Court.

C. The Defendant shall not violate the rules of the Henry County Detention Center or the Henry County Annex while incarcerated therein or under the jurisdiction thereof.

D. The probation supervision officer shall advise the Defendant that the Court may, at any time, revoke or modify any conditions of the probation and/or discharge the Defendant from probation. The probationer shall be subject to arrest for violation of any conditions of probation ordered by the Court. If such probation is revoked, the Court may order the execution of the sentence which was originally imposed or any portion thereof, in the manner provided by law, after deducting therefrom the amount of time Defendant has served on probation.

E. All payments are to be paid through the Court's designated provider of supervision services at a rate to be determined by the probation supervising officer and beginning at such time as may be designated by the probation supervising officer. All court costs, costs of extradition or apprehension related to violation of probation by Defendant will be assessed against Defendant.

F. The above and foregoing general conditions of probation shall remain in effect with respect to each case, until the further Order of this Court. These general conditions of probation shall be in addition to, and not in lieu of, any other conditions of probation which the Court may impose in Defendant's sentence for each case.

G. Each special condition of probation imposed on the face of this sentence is imposed as to all counts upon which Defendant is sentenced.

H. A copy of this Order along with a copy of the Court's sentence shall be given to each Defendant and each Defendant shall acknowledge in writing, by an appropriate form to be supplied by the probation supervising officer, that Defendant has received said items.

I. Defendant is hereby notified that any habeas corpus petition challenging the legality of this conviction must be filed within one year from the date of this sentence pursuant to O.C.G.A. § 9-14-42 (six months for traffic offenses).

SO ORDERED, this the _____ day of _____ 20____

VINCENT A. LOTTI, Chief Judge
State Court of Henry County

CHAUNDRA D. LEWIS, Judge
State Court of Henry County

STEPHEN N. KNIGHTS, JR., Judge
State Court of Henry County

RALPH BAILEY JR, Judge
State Court of Henry County

rev. 11/2022

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/23/2024		GA	Macon	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2024-0842		Georgia Board of Nursing		
Reason/Charge				
Public Consent Order				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jorge Menjivar				
Name of Business/Industry/Entity				

Provide explanation below:

On or about November 2, 2023, Respondent was found guilty of O.C.G.A. § 40-6-391 (a)(5)
Driving Under the Influence, O.C.G.A. § 40-6-391(a)(l) Driving Under the Influence of the Alcohol to the Extent it is Less Safe for the Person to Drive, and O.C.G.A. § 40-6-48 Failure to Maintain Lane. State of Georgia vs. Jorge Roberto Menjivar, Criminal Action No. 2022-ST-SR-4113-SNK. On or about December 20, 2023. Respondent voluntarily enrolled in the GNA-PNP. Soon thereafter, on or about December 27, 2023, Respondent disclosed his arrest to the Board. On or about April I, 2024, Respondent was ordered by the Board to submit to a Mental and Physical Evaluation (MPE). On or about April 16, 2024, Respondent submitted to the MPE. Respondent was diagnosed with alcohol dependence, uncomplicated. Respondent was found safe to practice with continuing treatment.
CONCLUSIONS OF LAW
The Respondent's conduct and/or condition outlined in the above Findings of Facts constitute(s) sufficient grounds for the imposition of conditions upon the Respondent's license to practice nursing as a registered professional nurse in the State of Georgia, under O.C.G.A. Chapter 26, Title 43.
ORDER
Effective 10/28/2024, my license to practice nursing as a registered professional nurse was placed on probation with terms and conditions such as: Required Courses, Required Enrollment with reports, Enrollment in Affinity Monitoring Program, Quarterly Reports from Employer, Personal Quarterly Reports, Participation in Psychotherapy and Quarterly Reports, Restrictions Concerning Agency/Private Duty Employment, and Abstain from Alcohol/Controlled Substances, Mood Altering Substances.

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/13/2025
Date

Professional Licensing
Boards

OCT 2 8 2024

Docket Number
2024-0842

BEFORE THE GEORGIA BOARD OF NURSING
STATE OF GEORGIA

IN THE MATTER OF:	*	
	*	DOCKET NO.:
JORGE MENJIVAR,	*	
License No. RN204394,	*	
	*	
Respondent.	*	

PUBLIC CONSENT ORDER

By agreement of the Georgia Board of Nursing, (hereinafter "Board"), and JORGE MENJIVAR, (hereinafter "Respondent"), the following disposition of this disciplinary matter is entered pursuant to the provisions of the Georgia Administrative Procedure Act, O.C.G.A § 50-13-13(a)(4), as amended.

FINDINGS OF FACT

1.

The Respondent is licensed to practice nursing as a registered professional nurse in the State of Georgia and was so licensed at all times relevant to the matters stated herein. Of note, Respondent has a license to practice in California, RN816908.

2.

On or about November 2, 2023, Respondent was found guilty of O.C.G.A. § 40-6-391(a)(5) Driving Under the Influence, O.C.G.A. § 40-6-391(a)(1) Driving Under the Influence of the Alcohol to the Extent it is Less Safe for the Person to Drive, and O.C.G.A. § 40-6-48 Failure to Maintain Lane. *State of Georgia vs. Jorge Roberto Menjivar*, Criminal Action No. 2022-ST-SR-4113-SNK. On or about December 20, 2023, Respondent voluntarily enrolled in the GNA-PNP. Soon thereafter, on or about December 27, 2023, Respondent disclosed his arrest to the Board.

3.

On or about April 1, 2024, Respondent was ordered by the Board to submit to a Mental and Physical Evaluation (MPE). On or about April 16, 2024, Respondent submitted to the MPE. Respondent was diagnosed with alcohol dependence, uncomplicated. Respondent was found safe to practice with continuing treatment.

4.

Respondent admits the above Findings of Fact and waives any further findings of fact with respect to the above-styled matter.

CONCLUSIONS OF LAW

The Respondent's conduct and/or condition outlined in the above Findings of Facts constitute(s) sufficient grounds for the imposition of conditions upon Respondent's license to practice nursing as a registered professional nurse in the State of Georgia, under O.C.G.A. Chapter 26, Title 43.

ORDER

Upon the effective date of this Consent Order, the Respondent's license to practice nursing as a registered professional nurse shall be placed on probation subject to the following terms and conditions:

1.

REQUIRED COURSES

(a) Coursework. Within **ninety (90) days** of the docket date of this Consent Order, the Respondent shall provide to the Board proof of successful completion of the following nursing education course: **Article on Understanding the Disease of Addiction**, which can be found at

http: www.nesbn.org. Documentation of successful completion of the nursing education courses shall be submitted to the Georgia Board of Nursing at 237 Coliseum Drive, Macon, GA 31217-3858, in care of the Legal/Disciplinary Nurse Consultant. **Failure to provide documentation of completion of the nursing education course(s) within ninety (90) days shall be deemed a violation of this Consent Order and shall subject the Respondent's license to further disciplinary action.**

REQUIRED ENROLLMENTS WITH REPORTS

(b) Participation in Treatment/Aftercare Program with Quarterly Reports. Throughout the duration of probation, the Respondent shall participate in a structured aftercare program for chemical dependence approved by the Board. Respondent's participation in such program shall be viewed as a condition precedent to all other provisions set forth herein, and the Respondent's failure to comply with that requirement, upon substantiation thereof, shall subject the Respondent's license to revocation. **The Respondent shall not change aftercare provider without submitting to the Board a letter of permission from the current aftercare facilitator, and receiving from the Board a letter approving a change of aftercare provider.**

The Respondent shall provide a copy of this Order to Respondent's program facilitator and shall cause Respondent's program facilitator to submit quarterly reports to the Board by March 31, June 30, September 30, and December 31, commencing on the first reporting date following the effective date of this Order and continuing throughout the period of probation. The reports shall evaluate Respondent's progress in rehabilitation and each quarterly report shall contain the results of the following tests/screens: **Respondent shall undergo TWICE MONTHLY urine drug screens, to include EtS and EtG, for the first twenty-four (24) months of the probationary period, then MONTHLY screens throughout the duration of**

the probationary period and MONTHLY PEth screens for the first twenty-four (24) months of the probation period. All positive screens will be reported to the Board. The quarterly reports shall include a disclosure of any medication being administered to the Respondent or prescribed as treatment for any illness of the Respondent. Respondent agrees that the receipt of a positive alcohol/drug screen and/or a report from the Respondent's program counselor that the Respondent has failed to comply with the requirements of the program and/or that the Respondent is otherwise unable to function as a registered professional nurse shall constitute reasonable grounds for the Board to order the Respondent to undergo a mental/physical examination and may also be reasonable grounds for disciplinary action, including summary suspension. Reports submitted pursuant to this paragraph shall be deemed medical records and shall not be subject to disclosure by the Board. In the event the reports are used in a subsequent hearing, they shall be received *in camera.*

(c) Enrollment in Affinity Monitoring Program or a program pre-approved by the Board with quarterly reports for alcohol and drug screens. Within **thirty (30) days** of the docket date of this Consent Order, Respondent agrees to enroll and participate in the Georgia Nurses Association's ("GNA") Affinity Monitoring Program or a similar random drug screening program pre-approved by the Board at Respondent's expense for the monitoring of random alcohol and drug screens throughout the period of probation. Respondent shall provide a copy of this Order to the GNA or the program chosen by Respondent and approved by the Board at the time of enrollment in the Affinity Monitoring Program or the similar monitoring program. Respondent shall be screened for any controlled substance for which Respondent has not provided a prescription. Respondent shall cause GNA or the drug screening monitoring program chosen by the Respondent and approved by the Board to provide **quarterly reports as provided in**

paragraph (b) above. Receipt of a positive alcohol/drug screen by the Board and/or a failure to participate in the Affinity Monitoring Program or a similar monitoring program that has been approved by the Board shall be deemed to be a violation of this Consent Order. The Respondent acknowledges and agrees that all of the Respondent's alcohol/drug screen reports received by the Board during the period of probation shall be admissible in any administrative hearing concerning the Respondent, without the necessity of establishing chain of custody or receiving other supporting testimony.

ADDITIONAL REQUIRED REPORTS

(d) Quarterly Reports from Employers. If the Respondent is employed as a nurse, the Respondent shall provide a copy of this Order to each of such employers or supervisors within ten (10) days of the Respondent's receipt of a docketed copy of the document. The Respondent shall cause such employers or supervisors to submit quarterly reports to the Board by March 31, June 30, September 30, and December 31, commencing on the first reporting date following the effective date of this Order and continuing throughout the period of probation. Each report shall evaluate the Respondent's performance of Respondent's duties. The receipt of an unfavorable report shall be deemed a violation of this Order and, upon substantiation thereof, shall be grounds for sanction or revocation of Respondent's license. Respondent is under a continuing duty to provide a copy of this Consent Order to any new employer **prior to accepting nursing employment.**

(e) Personal Quarterly Reports. The Respondent shall submit personal quarterly reports to the Board by March 31, June 30, September 30, and December 31, commencing on the first reporting date following the effective date of this Order and continuing throughout the period of

probation. Failure to submit such reports, upon substantiation thereof, shall be grounds for sanction or revocation of Respondent's license.

(f) Participation in Psychotherapy and Quarterly Reports. Throughout the period of probation or until discharged by his psychiatrist, whichever occurs first, Respondent shall participate in a program of psychotherapy with a psychiatrist, approved by the Board, specializing in addiction medicine. The Respondent shall provide a copy of this Order to the Respondent's psychiatrist and shall cause such individual to submit quarterly reports to the Board by March 31, June 30, September 30 and December 31, commencing on the first reporting date following the effective date of this Order and continuing through the period of probation, which reports shall evaluate the Respondent's progress in therapy. Upon discharge from therapy, the Respondent shall provide the Board with evidence of such discharge. The receipt of a report from the Respondent's psychiatrist that the Respondent has failed to comply with the program of therapy or that the Respondent is otherwise unable to function in a nursing capacity shall be grounds for further disciplinary action. Reports submitted pursuant to this paragraph shall be deemed medical records and shall not be subject to disclosure by the Board. In the event the reports are used in a subsequent hearing, they shall be received in camera.

OTHER RESTRICTIONS

(g) Restrictions Concerning Agency/Private Duty Employment. Respondent shall not be employed in any of the following settings without prior written approval of the Board: (1) assignments through a nursing agency or pool, (2) private duty nursing, (3) in-home nursing, (4) internal float pools, (5) travel assignments, or (6) in-home hospice care.

(h) Abstain from Alcohol, Controlled Substances, and Mood-Altering Substances. Respondent shall completely abstain from the consumption of alcohol, mood altering substances,

and shall abstain from the consumption of controlled substances except as prescribed by a duly licensed practitioner for a legitimate purpose. Should the Respondent be prescribed any controlled substances, a written report from the prescribing physician shall be submitted to the Board and to the Respondent's aftercare program counselor within ten (10) days of the prescribing thereof. **The Respondent must use caution when consuming or using products that contain alcohol, THC, Kratom, and/or opioids. These products may produce a positive result on a toxicology screen and will be considered a positive drug test in violation of the terms of this Order. Examples of these products include foods containing alcohol, such as vanilla extract, wine vinegar, and kombucha drinks; hygiene products containing alcohol such as mouthwashes and hand sanitizers; OTC medications containing alcohol such as Nyquil and Diphenhydramine Elixir; products containing THC such as CBD oil and Hemp oil, and foods containing opiates such as poppy seeds.**

(i) Use of Buprenorphine, medications containing Buprenorphine or medical marijuana pursuant to a prescription. While this Consent Order is in effect, Respondent may be treated with Buprenorphine, medications containing Buprenorphine, including but not limited to Suboxone, Subutex, Bunavail, Zubsolv, or Butrans, or medical marijuana pursuant to a prescription only with written approval by the Board.

If taking Buprenorphine, medications containing Buprenorphine, or medical marijuana pursuant to a prescription *prior* to the effective date of this Consent Order, to obtain approval, Respondent must provide a statement to the Board **within 10 days of the effective date of the Consent Order** from a physician who is board certified in addiction medicine that Respondent is safe to practice while taking Buprenorphine, medications containing Buprenorphine or medical marijuana. If prescribed Buprenorphine, medications containing Buprenorphine or medical

marijuana *after* the effective date of the Consent Order, to obtain approval, Respondent must provide a statement to the Board **within 10 days from the prescription** date from a physician who is board certified in addiction medicine that Respondent is safe to practice while taking Buprenorphine, medications containing Buprenorphine or medical marijuana.

Failure to receive written Board approval for practicing while taking Buprenorphine, medications containing Buprenorphine, or medical marijuana may result in further disciplinary action by the Board, including summary suspension or revocation.

OTHER OBLIGATIONS

(j) Copy of Consent Order to Director of Nursing Education Course. If the Respondent should be enrolled in any clinical nursing course, the Respondent shall also provide a copy of this Consent Order to the dean or director of such program.

(k) Reporting Requirements. Respondent shall provide a copy of this Consent Order to all reporting individuals. It shall be the responsibility of the Respondent to ensure that all required reports are timely submitted to and received by the Georgia Board of Nursing. **The preferred way to submit the reports is by email: Nursingcompliance@sos.ga.gov. They may also be sent to 237 Coliseum Drive, Macon, Georgia 31217-3858** in care of the Legal/Disciplinary Nurse Consultant. The Respondent shall report to the Board any change in Respondent's place of employment, residence, and current status as a practicing nurse within ten (10) days of said change.

(l) Abide by Laws, Rules, and Terms of Consent Order. If the Respondent shall fail to abide by all State and federal laws relating to drugs and regulating the practice of nursing in the State of Georgia, the Rules and Regulations of the Georgia Board of Nursing and the terms of this Consent Order, or if it should appear from reports submitted to the Board that the Respondent is

unable to practice as a registered professional nurse with reasonable skill and safety to patients, Respondent's license may be sanctioned or revoked, upon substantiation thereof.

(m) Consent to Release of Information. By executing this Consent Order, Respondent specifically consents to any individuals or entities reporting to the Board information which would affect Respondent's ability to practice as a nurse with reasonable skill and safety to patients or which constitutes a violation of the Nurse Practice Act or this Consent Order, notwithstanding any privilege provided by state or federal law, and agrees to provide to the Board any release or other documentation which may be necessary for the Board to obtain such information.

(n) Requirement to Keep Address Current. Pursuant to Board Rule 410-1-.03(2), Respondent agrees to maintain a current mailing address, email address and phone number with the Board. Respondent shall report to the Board in writing any changes in Respondent's mailing address, email address or phone number within 30 days of said change and shall make such changes on the Board's website. **Failure to change the Respondent's address, email or phone number on the Board's website shall be a violation of this Consent Order and will subject Respondent to disciplinary action, including indefinite suspension or revocation.**

(o) Effective date. The effective date of this Consent Order is the date the Consent Order is docketed. Respondent should receive a docketed copy of the Consent Order from the Board at Respondent's address of record within 10 business days of the docket date. If Respondent has not received a docketed copy of the Consent Order, it is Respondent's responsibility to obtain a docketed copy of the Consent Order from the Board. Respondent must comply with the terms and conditions of the Consent Order beginning on the effective date.

(p) Review of Consent Order. After acceptance by the Board and docketing, a copy of the docketed Consent Order shall be mailed to the Respondent. The Board will forward a Consent Order Review Form to Respondent. Within **ten (10) days** of the Respondent's receipt of such form, the Respondent shall submit the completed form to the Board. **Failure to comply with this requirement shall be deemed a violation of this Consent Order.**

TERMINATION

(q) Termination of Period of Probation. Respondent shall not be eligible to petition for termination of the period of probation until Respondent can document **five (5) years** of continuous sobriety immediately preceding the petition. At such time, Respondent may petition for termination by certifying under oath before a notary public that Respondent has complied with all conditions of the period of probation and by providing documentation supporting discharge from the period of probation, including but not limited to, a written statement from Respondent's aftercare counselor indicating that said counselor agrees with the termination of the period of probation, that Respondent is in good recovery, has been a continuous and compliant participant in a substance abuse program for the **five (5) years** preceding the petition, and is deemed able to practice nursing with skill and safety to the public. The Board shall review and evaluate the practice of Respondent prior to terminating the period of probation. At such time, should the Board determine that reasonable cause exists for maintaining probation on Respondent's license, the Board shall notify Respondent of its intent to extend the period of probation, and Respondent may respond to such notice in writing or request an appearance before the Board as in a non-contested case. In any event, this Consent Order shall remain in effect pending a final written determination by the Board and notification that the period of probation has been terminated.

2.

Approval of this Consent Order by the Georgia Board of Nursing shall not be construed as a waiver of any of the lawful rights possessed by the Board.

3.

The Respondent has read this Consent Order and understands its contents. Respondent understands that Respondent has the right to a hearing in this matter, and freely, knowingly and voluntarily waives such right by entering into this Consent Order. Respondent understands that this Consent Order will not become effective until approved by the Georgia Board of Nursing and docketed by the Division Director, Professional Licensing Boards Division. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering the Consent Order. Respondent understands that this Consent Order, once approved and docketed, shall constitute a **PUBLIC ORDER**, evidencing disciplinary action by the Board. However, if the Consent Order is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the Board's ability to adjudicate this matter. Respondent hereby consents to the terms and sanctions contained herein.

Approved this 23 day of October, 2024.

GEORGIA BOARD OF NURSING

[SIGNATURES ON NEXT PAGE]

BY: Ashlan Porter, BSN, RN

ASHLAN PORTER, BSN, RN
President

ATTEST: Todd J. Zandrowicz signed with express permission

TODD J. ZANDROWICZ
Division Director
Professional Licensing Boards Division

CONSENTED TO: [redacted]

JORGE MENJIVAR
Respondent

[As to Respondent's signature only:]
Sworn to and subscribed
before me this 15 day
of October, 2024.

APRIL CARROLL
Notary Public, Georgia
Henry County
My Commission Expires
October 12, 2027

NOTARY PUBLIC
My commission expires:
OCT 12 2027

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
09/06/2024		NV		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2024080115		Nevada State Board of Nursing		
Reason/Charge				
Agreement for Monitoring				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Jorge Menjivar				
Name of Business/Industry/Entity				

Provide explanation below:

The Nevada State Board of Nursing notified of entering/docketing of Georgia Board of Nursing Public Consent Order. Georgia Board of Nursing Consent Order terms reviewed and accepted by the Nevada State Board of Nursing.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/13/2025

Date

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF JORGE MENJIVAR LICENSED PROFESSIONAL NURSE NEVADA LICENSE NUMBER: RN 865069 RESPONDENT	AGREEMENT FOR MONITORING CASE NO. 2024080115

This Agreement is hereby entered into between JORGE MENJIVAR, (RESPONDENT) and the NEVADA STATE BOARD OF NURSING, (BOARD).

It is hereby stipulated and agreed, by and between the parties to the above-entitled matter, that the following statements are true:

1. Respondent is aware of, understands, and has been advised of the effect of this Agreement, which Respondent herein has carefully read and fully acknowledges. No coercion has been exerted on the Respondent. Respondent acknowledges their right to an attorney at their own expense. Respondent has had the benefit at all times of obtaining advice from the competent counsel of their choice.
2. Respondent understands the nature of the allegations under investigation by the Nevada State Board of Nursing. Respondent freely admits that they have been convicted for driving under the influence of alcohol twice between 2019 and 2023. Furthermore, they are a participant in the Georgia Board of Nursing Peer Assistance Program. Respondent acknowledges this conduct constitutes a violation of the Nevada Revised Statutes 632.347 (1)(m) action in another state. Respondent further acknowledges that such acts and admissions subject them to disciplinary action by the Board.
3. Respondent is aware of the Respondent's rights, including the right to a hearing on any charges and allegations, the right to an attorney at their own expense, the right to examine witnesses who would testify against them, the right to present evidence in their favor and call witnesses on their behalf, or to testify themself, the right to contest the charges and

allegations, the right to reconsideration, appeal or any other type of formal judicial review of this matter, and any other rights which may be accorded to them pursuant to the Nevada Administrative Procedures Act and the provisions of Chapter 632 of the Nevada Revised Statutes and the Nevada Administrative Code. **Respondent agrees to waive the foregoing rights upon acceptance of this Agreement by the Board.**

4. Respondent understands that the Board is free to accept or reject this Agreement, and if rejected by the Board, a disciplinary proceeding may be commenced. It is agreed that presentation to and consideration by the Board of such proposed Agreement, shall not disqualify the Board, or any of its members, from further participation, consideration, adjudication, or the resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias therefore. This Agreement shall only become effective when both parties have duly executed it, and unless so executed, this Agreement will not be construed as an admission.
5. This Agreement shall not be construed as excluding or reducing any criminal or civil penalties or sanctions, or other remedies that may be applicable under federal, state, or local laws.
6. This Agreement shall cover any nursing license or certificate issued by the State of Nevada. Based upon the foregoing stipulations and recitals, it is hereby agreed that the Board may issue the following decision and order:

DECISION AND ORDER

IT IS HEREBY ORDERED that the license in the name of JORGE MENJIVAR is placed on monitoring with the following terms and conditions for the amount of time remaining on their Georgia agreement until documentation of successful completion of the Georgia Board of Nursing Peer Assistance Program has been received, or they have completed all requirements herein:

1. COMPLIANCE WITH THE GEORGIA BOARD OF REGISTERED NURSING PEER ASSISTANCE PROGRAM (QUARTERLY REPORTS)

Respondent shall comply with all terms and conditions of their contract with the Georgia Board of Nursing Peer Assistance Program for impaired nurses and direct an authorized representative of the program to submit quarterly reports to the Board no later than the last day of March, June, September, and December addressing Respondent's contract compliance including copies of the results of their drug screens.

2. COMPLETION OF COURSES

Respondent shall take, and submit documentation of successful completion of the National Council of State Board of Nursing Nevada Nurse Practice Act course **within (30) days** of acceptance and execution of the Agreement by the Board.

3. VIOLATIONS OF THIS AGREEMENT - CONSEQUENCES

Respondent shall report any and all violations of the Georgia Board of Nursing Peer Assistance Program contract and/or this Agreement for Monitoring in writing to the Executive Director, or the Director of Investigations and Discipline and the Monitoring and Probation Investigator within seventy-two (72) hours of the occurrence. Respondent acknowledges that if they violate any of the terms and conditions of this Agreement, the Board may revoke, or invoke other appropriate discipline against their license to practice nursing, subject to a hearing in accordance with the Nevada Nurse Practice Act for the purpose of establishing that there has, in fact, been a violation of the stipulations of this Agreement. Respondent acknowledges that any violation of the Nevada Nurse Practice Act, any dilute urine or positive drug screen may be considered a violation of this Agreement and subject the respondent to further action by the Board.

4. AGREEMENT TO SURRENDER LICENSE

In the event that a violation of the terms and conditions of this Agreement is alleged, Respondent agrees to surrender their Nevada license to the Executive Director, or the Director of Investigations and Discipline and the Monitoring and Probation Investigator, if they so request, and refrain from practicing nursing in Nevada or with clients in Nevada until entry of a final

order of the Board or a court of competent jurisdiction, whichever last occurs, regarding a potential violation.

5. **COMPLETION AND TERMINATION OF MONITORING**

Respondent shall only receive credit toward service of their monitoring period in Nevada while employed in a capacity for which nursing licensure is required, and while working with clients/patients in Nevada, and/or while in compliance with the terms and conditions of their contract with the Georgia Board of Nursing Peer Assistance Program. Respondent acknowledges they are not eligible for early termination of this Agreement. The Agreement shall be terminated at the time the Board receives documentation verifying the Respondent's completion of all terms and conditions of the Monitoring Agreement and when the respondent receives notice of termination from the Board.

6. **MOVING TO THE STATE OF NEVADA (REQUIREMENTS)**

Respondent shall comply with the following terms and conditions effective immediately upon moving to the state of Nevada:

7. **ABSTINENCE AND DRUG TESTING**

Respondent shall abstain from the use of alcohol and all mood-altering drugs and controlled substances except when legally prescribed by a treating practitioner who is knowledgeable about the disease of addiction and the Respondent's history. This treatment must be reported to the Board, in writing, within seven (7) days, accompanied by documentation from the practitioner regarding the medical treatment and all other methods of alternative treatment having been tried first. The Board may require additional testing and reporting until Respondent documents sobriety after periods of prescribed drug use.

Respondent shall register with the Board-approved drug-screening program and submit to random urine, blood, or other tests for drugs of abuse and/or alcohol on the day requested by the drug testing company, their counselor, or representative of the Board. These tests shall occur no less than twenty-four (24) times per year and shall be treated as forensic specimens by a Board-approved laboratory. Respondent shall cause test results to be provided to the requesting party and the Board. Any confirmed positive finding shall be reported immediately to the Board.

Changes in the frequency of tests may be approved by the Director of Investigations and Discipline and the Monitoring and Probation Investigator.

8. **ATTENDANCE AT MEETINGS AND SUBMISSION OF QUARTERLY REPORTS TO THE BOARD**

Respondent shall comply with required attendance at meetings and shall cause all reports to be submitted in writing to the Board on a quarterly basis as follows. These reports are due no later than the last day of March, June, September, and December. The Executive Director, or the Director of Investigations and Discipline and the Monitoring and Probation Investigator may evaluate and approve or deny changes in the frequency of reporting. Respondent shall:

a. Attend a minimum of two (2) meetings per week of Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) and shall submit documentation of all meetings attended, **whether working or not.** The Monitoring and Probation Investigator will evaluate consideration for alternative recovery support groups;

b. Cause their AA or NA sponsor to submit reports addressing Respondent's progress in recovery on forms provided by the Board **whether working or not;**

c. Attend weekly meetings of a Board-approved Nurse Support Group and submit documentation of all meetings attended, **whether working or not;**

d. Submit self-reports in a detailed format as provided by the Board, **whether working or not;**

9. **REQUIREMENT TO ATTEND ORIENTATION AND MEET WITH THE BOARD OR STAFF**

Respondent shall attend a **mandatory orientation** meeting within thirty days of execution of this agreement to facilitate understanding and accountability of the terms and conditions of this Agreement as scheduled by the Monitoring and Probation Investigator. Upon request, Respondent shall meet with the Board or its representatives and cooperate with representatives of the Board in their supervision and investigation of Respondent's compliance with the terms and conditions of this Agreement.

10. **FINANCIAL RESPONSIBILITIES**

Respondent shall be financially responsible for all requirements of this Agreement. Respondent has reviewed and understands the potential costs associated with the stipulations herein. Respondent understands these costs are subject to change and are respondent's financial responsibility.

11. **REQUIRED NOTIFICATION OF OTHER STATES OF LICENSURE**

Respondent shall, upon execution of this Agreement, provide a copy of this Agreement to any other state Board of Nursing in whose jurisdiction they have been issued a nursing license (current or not). Respondent shall also provide a copy of this Agreement to any other regulatory agency in whose jurisdiction they have applied or will apply for a license.

12. **VIOLATIONS OF THIS AGREEMENT - CONSEQUENCES**

Respondent acknowledges that if they violate any of the terms and conditions of this Agreement, the Board may revoke, or invoke other appropriate discipline against their license to practice nursing, subject to a hearing in accordance with the Nevada Nurse Practice Act for the purpose of establishing that there has, in fact, been a violation of the stipulations of this Agreement. Respondent acknowledges that any violation of the Nevada Nurse Practice Act, any dilute urine or positive drug screen may be considered a violation of this Agreement and subject the respondent to further action by the Board. A positive drug screen will result in immediate suspension of license. Suspension of the license is considered disciplinary action and will become part of the Respondent's permanent record, will become public information, will be published with the list of disciplinary actions taken against licensees or holders of certificates, or any agency or another state which regulates the practice of nursing.

13. **AGREEMENT TO SURRENDER LICENSE**

In the event that a violation of the terms and conditions of this Agreement is alleged, Respondent agrees to surrender their license to the Executive Director, or the Director of Investigations and Discipline and the Monitoring and Probation Investigator, if they so request, and refrain from practicing nursing until requirements have been met, violations resolved, or

entry of a final order of the Board or a court of competent jurisdiction, whichever last occurs, regarding a potential violation.

Respondent acknowledges that pursuant to NRS 632.405, this Agreement shall become a public record if an entry of a final order of the Board results in disciplinary action against their license for violation of this agreement.

14. **COMPLETION AND TERMINATION OF MONITORING**

Respondent shall only receive credit toward service of their probation period while employed in a capacity for which nursing licensure is required and subject to adequate supervision approved by the Board. Respondent acknowledges they are not eligible for early termination of this Agreement. The Agreement shall be terminated at the time the Board receives documentation verifying the Respondent's completion of all terms and conditions of the Probation Agreement and when the respondent receives notice of termination from the Board.

///

The NEVADA STATE BOARD OF NURSING retains jurisdiction in this case until all conditions have been met to the satisfaction of the Board.

Dated this 3 day of September, 2024

[redacted]

RESPONDENT'
JORGE MENJIVAR

State of ~~Nevada~~ Georgia

County of Henry

This instrument was acknowledged before me on September 3, 2024, by Jorge Menjivar.

TIFFANY HURLEY
Notary Public, Georgia
Henry County
My Commission Expires
October 18, 2027

Notary Public

Accepted and approved this 6th day of September, 2024

NEVADA STATE BOARD OF NURSING

By: Cathy Dinauer
Cathy Dinauer, MSN, RN
Executive Director

Costs Associated with Alcohol/Drug Testing

Per your agreement **"Respondent shall register with the Board approved drug-screening program and submit to random urine, blood or other tests for drugs of abuse and/or alcohol."** Potential costs related to drug testing is outlined below.

Your Agreement	Description of Costs Per Test	Reno	Las Vegas	Elko
X	Affinity fee for drug testing urine sample	$43	$43	$43
X	Urine collection fee at site	$15 - $43	$20 - $43	$40
	Total cost per test	**$58 - $86**	**$63 - $86**	**$83**
Other Tests that may be Requested				
Blood testing of sample for PEth		$136	$136	$136
Blood collection fee at site		$10 - $53	$10 - $53	$25
Total cost per test		**$146 - $189**	**$146 - $189**	**$161**
Hair/nail drug testing 5 panel		$91	$91	$91
Hair/nail drug testing 7 panel		$131	$131	$131
Hair/nail drug testing 10 panel		**$151**	**$151**	**$151**
Hair/nail drug testing 12 panel		$256	$256	$256
Hair/nail drug testing 14 panel		$281	$281	$281
Add hair/nail collection fee at site		**$15 - $47**	**$25 - $47**	**$25**

Estimated average cost per month for: Jorge Menjivar (in the event of relocation to Nevada)

Requirement	Cost per event	Minimum events per month	Total per month
Urine drug screen	$63 - $86	2	$116 - $172
Total Average Cost per Month			**$116 - $172**

I have reviewed and understand the potential costs associated with the Agreement for monitoring with the Board. I understand these costs are subject to change and are my financial responsibility.

[redacted]

Signed

9/3/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jorge Menjivar

Applicant Print Name (First, Last)

[redacted] 2/13/2025

Original Signature (electronic, copies or stamps not accepted) Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date

Board Use Only: Date Processed: 2/19/25 Amount: $200 ✓

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

JORGE ROBERTO MENJIVAR [NCSBN ID: 21373504]

Wednesday, March 12 2025 10:18:22 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MENJIVAR, JORGE ROBERTO	RN	865069	Inactive	02/28/2023	05/12/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MENJIVAR, JORGE ROBERTO	APRN-CNP	865069	Inactive	03/09/2023	05/15/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 05/15/2023
  - Original Issuance Date: 03/09/2023
  - Current Issue Date: 03/09/2023
  - Certification expiration date: 01/03/2027

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MENJIVAR, JORGE ROBERTO	RN	865069	Active	05/12/2023	08/11/2026	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MENJIVAR, JORGE ROBERTO	APRN-CNP	865069	Active	05/15/2023	08/11/2026	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 08/11/2026
  - Original Issuance Date: 05/15/2023
  - Current Issue Date: 09/11/2024
  - Certification expiration date: 01/03/2027

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

12B

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☒ Dangerous Drugs ONLY **(Non-Refundable $80 Fee) (PR)**

☐ Dangerous Drugs ~~AND~~ Controlled Substances (CS) I, II, III, IV and/or V **(Non-Refundable $200 Fee) (CS)**

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Samantha Middle: Jeanne Last: Perkins

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: [redacted]

Telephone: [redacted] Email: [redacted]

APRN License #: 884504 Specialty: Psychiatric-mental health

(A **current license and active-PRESCRIBING status** with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Journey Complete Care

Practice Address: 801 S RANCHO DR Suite #: STE B1B

City: LAS VEGAS State: NV Zip: 89106-3871

Telephone: 818-665-5199 Fax: _____ Email: [redacted]

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: _____

Collaborating Physician Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

N/P

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2022	UNK	CA	Orange	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
UNK	California Board of Nursing

Reason/Charge
Unprofessional Conduct

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

-I have provided all this information to the board of nursing in Nevada and they are aware, and they recommended that I need to inform them of the conculsion when I reapply for my license .

The 11/19/2024 Accusation filed by the Board of Registered Nursing is a charging document which contains allegations only, allegations which I believe have been blown out of proportion. Nothing has been proven, no findings or judgments have yet been made on the allegations, nor has any discipline yet been imposed on my license. It remains completely unrestricted, pending resolution of this case, which I am informed by my attorneys will not conclude for quite some time. I will soon be invoking my right to a formal administrative hearing to challenge the allegations and requesting copies of all the materials the Board is claiming support its allegations. At present, I have received no discovery from the Board and no hearing dates have been scheduled, let alone held. All of that is a ways away.

I can share that in general they arise from my issuance of a very limited number of bridge and/or emergency prescriptions to a co-worker with whom I was engaged in a long-term, marriage-equivalent domestic relationship, which had begun years before the first prescription was issued. All prescriptions were clinically indicated, short-term, and resulted in zero harm to the patient. To the contrary, several were life-saving in the context they were issued. Regarding the Board's criticisms of my standardized procedures and protocols, I dispute that they were inadequate or that my limited prescriptions constituted the unlicensed practice of medicine as a result.

Although I acknowledge that my conduct was not perfect in every respect, particularly my documentation, the Board's allegations are not reflective of the actual situation. Moreover, in the years intervening, I have proactively engaged in extensive rehabilitation activities, including completing several intensive, multi-day, board-approved seminars in record keeping, prescribing, and ethics; undergoing targeted personal psychotherapy focused on maintaining boundaries; and completing a mentoring program with an N.P./Ph.D., which was focused on ethical practice, patient safety, and professional standards. I have also completely changed my practice setting and I experienced zero issues in any setting or context since. In sum, I have a substantial amount of relevant defense evidence and I plan on vigorously defending this Accusation.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

1/7/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Samantha Perkins

[redacted]

Original Signature (electronic, copies or stamps not accepted)

1/7/25

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: 1/13/25 Amount: $200-cc

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
GREGORY J. SALUTE
Supervising Deputy Attorney General
State Bar No. 164015
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9431
Facsimile: (619) 645-2061
E-mail: Gregory.Salute@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS

STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 4002023003518
SAMANTHA JEANNE PERKINS	**STATEMENT TO RESPONDENT**
Respondent.	[Gov. Code §§ 11504, 11505(b)]

TO RESPONDENT:

Enclosed is a copy of the Accusation that has been filed with the Board of Registered Nursing of the Department of Consumer Affairs (Board), and which is hereby served on you.

Unless a written request for a hearing signed by you or on your behalf is delivered or mailed to the Board, represented by Supervising Deputy Attorney General Gregory J. Salute, within fifteen (15) days after a copy of the Accusation was personally served on you or mailed to you, you will be deemed to have waived your right to a hearing in this matter and the Board may proceed upon the Accusation without a hearing and may take action thereon as provided by law.

The request for hearing may be made by delivering or mailing one of the enclosed forms entitled "Notice of Defense," or by delivering or mailing a Notice of Defense as provided in section 11506 of the Government Code, to

Gregory J. Salute
Supervising Deputy Attorney General
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266

You may, but need not, be represented by counsel at any or all stages of these proceedings.

The enclosed Notice of Defense, if signed and filed with the Board, shall be deemed a specific denial of all parts of the Accusation, but you will not be permitted to raise any objection to the form of the Accusation unless you file a further Notice of Defense as provided in section 11506 of the Government Code within fifteen (15) days after service of the Accusation on you.

All communications from the Board will be sent to your address of record as shown in the caption page one of this document. It is your responsibility to advise the Board of any changes to your address of record.

If you file any Notice of Defense within the time permitted, a hearing will be held on the charges made in the Accusation.

The hearing may be postponed for good cause. If you have good cause, you are obliged to notify the Office of Administrative Hearings, Emerald Plaza, 402 West Broadway, Suite 600, San Diego, CA 92101, within ten (10) working days after you discover the good cause. Failure to notify the Office of Administrative Hearings within ten (10) days will deprive you of a postponement.

Copies of sections 11507.5, 11507.6, and 11507.7 of the Government Code are enclosed.

If you desire the names and addresses of witnesses or an opportunity to inspect and copy the items mentioned in section 11507.6 of the Government Code in the possession, custody or control of the Board you may send a Request for Discovery to the above designated Supervising Deputy Attorney General.

NOTICE REGARDING STIPULATED SETTLEMENTS

It may be possible to avoid the time, expense and uncertainties involved in an administrative hearing by disposing of this matter through a stipulated settlement. A stipulated settlement is a binding written agreement between you and the government regarding the matters

charged and the discipline to be imposed. Such a stipulation would have to be approved by the Board of Registered Nursing but, once approved, it would be incorporated into a final order.

Any stipulation must be consistent with the Board's established disciplinary guidelines; however, all matters in mitigation or aggravation will be considered A copy of the Board's Disciplinary Guidelines will be provided to you on your written request to the state agency bringing this action.

If you are interested in pursuing this alternative to a formal administrative hearing, or if you have any questions, you or your attorney should contact Supervising Deputy Attorney General Gregory J. Salute at the earliest opportunity.

Dated: December 3, 2024

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

GREGORY J. SALUTE
Supervising Deputy Attorney General
Attorneys for Complainant

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E-mail: Gregory.Salute@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SAMANTHA JEANNE PERKINS** [redacted] **Santa Ana, CA** [redacted] **Registered Nurse License No. 95052299** **Nurse Practitioner Certificate No. 95001938** **Nurse Practitioner Furnishing Certificate No. 95001938** Respondent.	Case No. 4002023003518 **ACCUSATION**

PARTIES

1. Loretta Melby, R.N., M.S.N. (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Registered Nursing, Department of Consumer Affairs.

2. On or about January 23, 2015, the Board of Registered Nursing issued Registered Nurse License Number 95052299 to Samantha Jeanne Perkins (Respondent). The Registered Nurse License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2026, unless renewed.

3. On or about January 23, 2015, the Board of Registered Nursing issued Nurse Practitioner Certificate Number 95001938 to Samantha Jeanne Perkins (Respondent). The Nurse Practitioner Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2026, unless renewed.

4. On or about March 7, 2015, the Board of Registered Nursing issued Nurse Practitioner Furnishing Certificate Number 95001938 to Samantha Jeanne Perkins (Respondent). The Nurse Practitioner Furnishing Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2026, unless renewed.

STATUTORY PROVISIONS

5. Section 726 of the Code states:

> (a) The commission of any act of sexual abuse, misconduct, or relations with a patient, client, or customer constitutes unprofessional conduct and grounds for disciplinary action for any person licensed under this division or under any initiative act referred to in this division.
>
> (b) This section shall not apply to consensual sexual contact between a licensee and his or her spouse or person in an equivalent domestic relationship when that licensee provides medical treatment, other than psychotherapeutic treatment, to his or her spouse or person in an equivalent domestic relationship.

6. Section 2242, subdivision (a), of the Code states:

> Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

7. Section 2725 of the Code states:

> (a) In amending this section at the 1973-74 session, the Legislature recognizes that nursing is a dynamic field, the practice of which is continually evolving to include more sophisticated patient care activities. It is the intent of the Legislature in amending this section at the 1973-74 session to provide clear legal authority for functions and procedures that have common acceptance and usage. It is the legislative intent also to recognize the existence of overlapping functions between physicians and registered nurses and to permit additional sharing of functions within organized health care systems that provide for collaboration between physicians and registered nurses. These organized health care systems include, but are not limited to, health facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, clinics, home health agencies, physicians" offices, and public or community health services.

(b) The practice of nursing within the meaning of this chapter [the Nursing Practice Act] means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:

(1) Direct and indirect patient care services that ensure the safety, comfort, personal hygiene, and protection of patients; and the performance of disease prevention and restorative measures.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

(3) The performance of skin tests, immunization techniques, and the withdrawal of human blood from veins and arteries.

(4) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures.

(c) "Standardized procedures," as used in this section, means either of the following:

(1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses.

(2) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

The policies and protocols shall be subject to any guidelines for standardized procedures that the Division of Licensing of the Medical Board of California and the Board of Registered Nursing may jointly promulgate. If promulgated, the guidelines shall be administered by the Board of Registered Nursing.

(d) Nothing in this section shall be construed to require approval of standardized procedures by the Division of Licensing of the Medical Board of California, or by the Board of Registered Nursing.

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(e) No state agency other than the board may define or interpret the practice of nursing for those licensed pursuant to the provisions of the chapter, or develop standardized procedures or protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal statute. A State agency includes every state office, officer, department, division, bureau, board, authority, and commission.

8. Section 2726 of the Code states that [e]xcept as otherwise provided herein, this chapter [the Nursing Practice Act] confers no authority to practice medicine or surgery.

9. Section 2761[1] of the Code states:

(a) The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:

(1) Unprofessional conduct, which includes, but is not limited to, the following:

(2) Incompetence or gross negligence in carrying out usual certified or licensed nursing functions.

...

10. Section 2762 of the Code states:

In addition to other acts constituting unprofessional conduct within the meaning of this chapter [the Nursing Practice Act], it is unprofessional conduct for a person licensed under this chapter to do any of the following:

(a) Obtain or possess in violation of law, or prescribe, or except as directed by a licensed physician and surgeon, dentist, or podiatrist administer to himself or herself, or furnish or administer to another, any controlled substance as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code or any dangerous drug or dangerous device as defined in Section 4022.

...

(e) Falsify, or make grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a) of this section.

11. Section 2836.1 of the Code states:

Neither this chapter, nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

[1] Business and Professions Code section 2761 was revised effective January 1, 2024. Former Section 2761(a) is now 2761(a)(1), and former Section 2761(a)(4) is now Section 2761(a)(2)(C).

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedures or protocols shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioners' competence, including peer review, and review of the provisions of the standardized procedure.

. . .

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of standardized procedure, (2) approval of standardized procedure, and (3) availability by telephone contact at the time of patient examination by the nurse practitioner.

. . .

12. Section 2836.2 of the Code states:

Furnishing or ordering of drugs or devices by nurse practitioners is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure. All nurse practitioners who are authorized pursuant to Section 2386.1 to furnish or issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration.

REGULATORY PROVISIONS

13. California Code of Regulations, title 16, section 1442, states:

As used in Section 2761 of the code, "gross negligence" includes an extreme departure from the standard of care which, under similar circumstances, would have ordinarily been exercised by a competent registered nurse. Such an extreme departure means the repeated failure to provide nursing care as required or failure to provide care or to exercise ordinary precaution in a single situation which the nurse knew, or should have known, could have jeopardized the client's health or life.

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14. California Code of Regulations, title 16, section 1443, states:

As used in Section 2761 of the code, "incompetence" means the lack of possession of or the failure to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by a competent registered nurse as described in Section 1443.5.

15. California Code of Regulations, title 16, section 1443.5 states:

A registered nurse shall be considered to be competent when he/she consistently demonstrates the ability to transfer scientific knowledge from social, biological and physical sciences in applying the nursing process, as follows:

(1) Formulates a nursing diagnosis through observation of the client's physical condition and behavior, and through interpretation of information obtained from the client and others, including the health team.

(2) Formulates a care plan, in collaboration with the client, which ensures that direct and indirect nursing care services provide for the client's safety, comfort, hygiene, and protection, and for disease prevention and restorative measures.

(3) Performs skills essential to the kind of nursing action to be taken, explains the health treatment to the client and family and teaches the client and family how to care for the client's health needs.

(4) Delegates tasks to subordinates based on the legal scopes of practice of the subordinates and on the preparation and capability needed in the tasks to be delegated, and effectively supervises nursing care being given by subordinates.

(5) Evaluates the effectiveness of the care plan through observation of the client's physical condition and behavior, signs and symptoms of illness, and reactions to treatment and through communication with the client and health team members, and modifies the plan as needed.

(6) Acts as the client's advocate, as circumstances require, by initiating action to improve health care or to change decisions or activities which are against the interests or wishes of the client, and by giving the client the opportunity to make informed decisions about health care before it is provided.

16. California Code of Regulations, title 16, section 1471, states:

For purposes of this article:

(a) "Standardized procedure functions" means those functions specified in Business and Professions Code Section 2725(c) and (d) which are to be performed according to "standardized procedures";

(b) "Organized health care system" means a health facility which is not licensed pursuant to Chapter 2 (commencing with Section 1250), Division 2 of the Health and Safety Code and includes, but is not limited to, clinics, home health agencies, physicians' offices and public or community health services;

///

///

(c) "Standardized procedures" means policies and protocols formulated by organized health care systems for the performance of standardized procedure functions.

17. California Code of Regulations, title 16, section 1472 states:

An organized health care system must develop standardized procedures before permitting registered nurses to perform standardized procedure functions. A registered nurse may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedures; and must provide the system with satisfactory evidence that the nurse meets its experience, training, and/or education requirements to perform such functions.

18. California Code of Regulations, title 16, section 1474 states:

Following are the standardized procedure guidelines jointly promulgated by the Medical Board of California and by the Board of Registered Nursing:

(a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.

(b) Each standardized procedure shall:

(1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.

(2) Specify which standardized procedure functions registered nurses may perform and under what circumstances.

(3) State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.

(4) Specify any experience, training, and/or education requirements for performance of standardized procedure functions.

(5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.

(6) Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.

(7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.

(8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.

(9) State the limitations on settings, if any, in which standardized procedure functions may be performed.

(10) Specify patient record keeping requirements.

(11) Provide for a method of periodic review of the standardized procedures.

COST RECOVERY

19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUG DESCRIPTIONS

20. **Clonazepam:** is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(7), and a dangerous drug pursuant to Business and Professions Code section 4022. It is an anti-anxiety medication in the benzodiazepine family.

21. **Zofran (Ondansetron):** blocks the actions of chemicals in the body that can trigger nausea and vomiting. Ondansetron is used to prevent nausea and vomiting that may be caused by surgery, cancer chemotherapy, or radiation treatment. It is a dangerous drug pursuant to Business and Professions Code section 4022.

22. **Oxcarbazepine:** is an anticonvulsant. It works by decreasing nerve impulses that cause seizures and pain. Oxcarbazepine is used either alone or with other medicines to treat partial seizures. The Trileptal brand of oxcarbazepine is used as a single medicine in adults and children who are at least 4 years old. Trileptal is used with other medicines in adults and children who are at least 2 years old. It is a dangerous drug pursuant to Business and Professions Code section 4022.

23. **Effexor (Venlafaxine):** is used in adults to treat major depressive disorder. Effexor XR extended-release (long-acting) capsules are also used to treat generalized anxiety disorder (GAD; excessive worrying that is difficult to control), social anxiety disorder (extreme fear of interacting with others or performing in front of others that interferes with normal life), and panic disorder (sudden, unexpected attacks of extreme fear and worry about these attacks). Effexor belongs to in a class of medications called selective serotonin and norepinephrine reuptake inhibitors (SNRIs). Venlafaxine works by increasing the amounts of serotonin and

norepinephrine, natural substances in the brain that help maintain mental balance. It a dangerous drug pursuant to Business and Professions Code section 4022.

STATEMENT OF FACTS

24. Respondent was employed at St. Joseph Hospital from October 2016 through October 2022. She worked in the Emergency Clinical Decision Unit (EDOC) as a Psychiatric Nurse Practitioner. Her job duties required her to conduct consultations for psychiatric patients in the Emergency Room.

25. Respondent prescribed medications to a co-worker (RB) without completing a good faith exam or creating a medical record. Respondent was also in a personal relationship with RB while he was under her care. The following prescriptions were written by Respondent to patient RB:

6/27/2020-Venlafaxine ER 37.5-Telephone order

3/19/2021 Clonazepam 0.5 mg

04/20/2022 oxcarbazepine 150mg

05/25/2022 oxcarbazepine 600mg

8/1/2022-ondansetron (Zofran)

26. Respondent admitted that in 2017, after approximately a year of working together, her and RB had a personal relationship. The relationship continued for approximately four and a half years. The personal relationship ended on or about October 2021. When questioned, RB denied that he was a patient of Respondent.

27. Respondent stated that they also had a provider-patient relationship. The services provided were writing prescriptions. Some were written through her job at Providence, and some were in her private practice. Respondent admitted to writing one controlled substance prescription, clonazepam to RB. This was the first prescription written, along with Effexor. Respondent also admitted to writing a prescription for oxcarbazepine for RB, which she referred to by the brand name Trileptal, later in 2022.

28. Respondent admitted RB was not a patient at Providence St Joseph Hospital when she wrote him the prescriptions for clonazepam and Effexor. In addition, Respondent failed to

maintain a patient chart for patient RB at Providence St Joseph Hospital. Her patient records for RB at her private practice Transcend Psychiatry were sparse and had no good faith exam or diagnosis or rationale for prescribing the medications to RB.

29. In response to the Board investigator's request for Standardized Procedures for Transcend Psychiatry, Respondent provided an unsigned, undated document titled "Standard Treatment Protocol" that did not meet the legal requirements for Standardized Procedures and failed to have any protocols for drugs she was authorized to furnish, as required by Code section 2836.1. The document also did not specify the protocols for Clonazepam, Effexor and Trileptal as required by Code section 2836.1.

30. Respondent's conduct was unprofessional and deviated from the standards of practice for the following reasons:

A. Respondent failed to assess the health status of patient RB. Respondent's encounter notes did not reflect the following:

1. Comprehensive relevant health, social and medical history.

2. Physical examination based on age and history, which includes head to toe assessment and mental status exam.

3. Mental Health Screening Tools to help Respondent identify signs of psychological disorders or distress in RB.

B. Respondent made a diagnosis and prescribed medications without utilizing a diagnostic reasoning, which is based on the patient's detailed history, physical assessment, and diagnostic and mental health screening tools.

C. Respondent failed to delineate and maintain boundaries. Respondent failed to work within the therapeutic relationship...Respondent should examine any boundary crossing, be aware of its potential implications, and avoid repeated crossings.

D. There was a personal relationship while Respondent was treating RB. Respondent admitted after about a year, in 2017 they had a personal relationship. The significant relationship continued for approximately four and a half years. Respondent stated that their relationship ended on or about October 2021.

E. Respondent practiced without valid Standardized Procedures and Collaborative agreement for her private practice, Transcend Psychiatry. She claimed she saw RB as a provider in her private practice and submitted encounter notes.

F. The following elements were missing in Respondent's submitted Standardized Procedures:

(1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.

. . .

(5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.

(6) Provide a method of maintaining a written record of those persons authorized to perform standardized procedure functions.

. . .

(8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.

(9) State the limitations on settings, if any, in which standardized procedure functions may be performed.

. . .

(11) Provide a method of periodic review of the standardized procedures.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Furnishing of Drugs Without Standardized Procedures)

31. Respondent is subject to discipline for unprofessional conduct pursuant to Code sections 2761, subdivision (a)(1), and 2836.1, in that without standardized procedures she furnished and/or ordered prescription drugs including controlled substances to RB. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

///

///

///

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Unauthorized Dispensing of Prescription Medications)

32. Respondent is subject to discipline for unprofessional conduct pursuant to Code sections 2761, subdivision (a)(1), and 2762, subdivision (a), in that without authorization she furnished and/or ordered prescription drugs including controlled substances to RB. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Practice of Medicine Without a License)

33. Respondent is subject to discipline for unprofessional conduct pursuant to Code sections 2761, subdivision (a)(1), and 2726, in that she furnished and/or ordered prescription drugs including controlled substances without appropriate standardized procedures in place authorizing her to furnish and/or prescribe said drugs to RB. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Submission of False Prescriptions)

34. Respondent is subject to discipline for unprofessional conduct pursuant to Code sections 2761, subdivision (a)(1), and 2762, subdivision (e), in that by furnishing and/or ordering prescription drugs including controlled substances to RB, Respondent falsely represented that she was the treating Nurse Practitioner. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Gross Negligence)

35. Respondent is subject to disciplinary action under Code section 2761, subdivision (a)(2), in conjunction with California Code of Regulations, title 16, section 1442, in that she was grossly negligent and demonstrated an extreme departure from the standard of care when she had sexual relations with RB while treating RB and while furnishing and/or ordering prescription drugs including controlled substances to RB without physician supervision. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Incompetence)

36. Respondent is subject to disciplinary action under Code section 2761, subdivision (a)(2), in conjunction with California Code of Regulations, title 16, section 1443, in that she was incompetent and failed to exercise that degree of learning, skill, care and experience ordinarily possessed and exercised by a competent registered nurse when she had sexual relations with RB while treating RB and while furnishing and/or ordering prescription drugs including controlled substances to RB without physician supervision. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Sexual Relations with an Individual Receiving Treatment from Respondent)

37. Respondent is subject to disciplinary action under Code section 726, in that she had sexual relations with RB while treating RB and while furnishing and/or ordering prescription drugs including controlled substances to RB who was not her spouse. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Prescribing a Controlled Substance Without a Good Faith Exam)

38. Respondent is subject to disciplinary action for unprofessional conduct under Code section 2761, subdivision (a)(1), in conjunction with Code section 2242 subdivision (a), in that she prescribed Clonazepam, a schedule IV-controlled substance to RB without a Good Faith Exam. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct –Boundary Violations)

39. Respondent is subject to disciplinary action for unprofessional conduct under Code section 2761(a)(1) in that she had sexual relations with RB while treating RB and while

furnishing and/or ordering prescription drugs including controlled substances to RB who was not her spouse. The facts in support of this cause for discipline are set forth above in paragraphs 24 through 30.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Registered Nursing issue a decision:

1. Revoking or suspending Registered Nurse License Number 95052299, issued to Samantha Jeanne Perkins;

2. Revoking or suspending Nurse Practitioner Certificate Number 95001938, issued to Samantha Jeanne Perkins;

3. Revoking or suspending Nurse Practitioner Furnishing Certificate Number 95001938, issued to Samantha Jeanne Perkins;

4. Ordering Samantha Jeanne Perkins to pay the Board of Registered Nursing the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

5. Taking such other and further action as deemed necessary and proper.

DATED: November 19, 2024

for LORETTA MELBY, R.N., M.S.N.
Executive Officer
Board of Registered Nursing
Department of Consumer Affairs
State of California
Complainant

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ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General
GREGORY J. SALUTE
Supervising Deputy Attorney General
State Bar No. 164015
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9431
Facsimile: (619) 645-2061
E-mail: Gregory.Salute@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 4002023003518
SAMANTHA JEANNE PERKINS	**REQUEST FOR DISCOVERY**
Respondent.	

TO RESPONDENT:

Under section 11507.6 of the Government Code of the State of California, parties to an administrative hearing, including the Complainant, are entitled to certain information concerning the opposing party's case. A copy of the provisions of section 11507.6 of the Government Code concerning such rights is included among the papers served.

PURSUANT TO SECTION 11507.6 OF THE GOVERNMENT CODE, YOU ARE HEREBY REQUESTED TO:

1. Provide the names and addresses of witnesses to the extent known to the Respondent, including, but not limited to, those intended to be called to testify at the hearing, and

2. Provide an opportunity for the Complainant to inspect and make a copy of any of the following in the possession or custody or under control of the Respondent:

a. A statement of a person, other than the Respondent, named in the initial administrative pleading, or in any additional pleading, when it is claimed that

the act or omission of the Respondent as to this person is the basis for the administrative proceeding;

b. A statement pertaining to the subject matter of the proceeding made by any party to another party or persons;

c. Statements of witnesses then proposed to be called by the Respondent and of other persons having personal knowledge of the acts, omissions or events which are the basis for the proceeding, not included in (a) or (b) above;

d. All writings, including but not limited to reports of mental, physical and blood examinations and things which the Respondent now proposes to offer in evidence;

e. Any other writing or thing which is relevant and which would be admissible in evidence, including but not limited to, any patient or hospital records pertaining to the persons named in the pleading;

f. Investigative reports made by or on behalf of the Respondent pertaining to the subject matter of the proceeding, to the extent that these reports (1) contain the names and addresses of witnesses or of persons having personal knowledge of the acts, omissions or events which are the basis for the proceeding, or (2) reflect matters perceived by the investigator in the course of his or her investigation, or (3) contain or include by attachment any statement or writing described in (a) to (e), inclusive, or summary thereof.

IN ADDITION, if cost recovery is requested in the pleading prayer, provide all writings which will support any objection which may be made by the Respondent, to Respondent's payment of investigation and enforcement costs to the Board.

For the purpose of this Request for Discovery, "statements" include written statements by the person, signed, or otherwise authenticated by him or her, stenographic, mechanical, electrical or other recordings, or transcripts thereof, of oral statements by the person, and written reports or summaries of these oral statements.

YOU ARE HEREBY FURTHER NOTIFIED that nothing in this Request for Discovery should be deemed to authorize the inspection or copying of any writing or thing which is privileged from disclosure by law or otherwise made confidential or protected as attorney's work product.

Your response to this Request for Discovery should be directed to the undersigned attorney for the Complainant at the address on the first page of this Request for Discovery within 30 days after service of the Accusation.

Failure without substantial justification to comply with this Request for Discovery may subject the Respondent to sanctions pursuant to sections 11507.7 and 11455.10 to 11455.30 of the Government Code.

Dated: December 3, 2024

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

GREGORY J. SALUTE
Supervising Deputy Attorney General
Attorneys for Complainant

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BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SAMANTHA JEANNE PERKINS** Respondent.	Case No. 4002023003518 **NOTICE OF DEFENSE** [Gov. Code §§ 11505 and 11506]

I, the undersigned Respondent in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Accusation; Statement to Respondent; Government Code sections 11507.5, 11507.6 and 11507.7, Complainant's Request for Discovery, and two copies of a Notice of Defense.

Date:	
Respondent's's Name:	
Respondent's's Signature:	
Phone:	
E-mail:	

NOTE: ALL COMMUNICATIONS WILL BE SENT TO YOUR ADDRESS OF RECORD WITH THE BOARD. ANY CHANGES TO YOUR ADDRESS OF RECORD MUST BE MADE DIRECTLY WITH THE BOARD.

Check appropriate boxes:

☐	I hereby request a hearing to permit me to present my defense to the Accusation.
☐	I wish to be considered for a stipulated settlement.
☐	I wish to surrender my license.
☐	I am represented by counsel, whose name, address and telephone number appear below:

	Counsel's Name:
	Counsel's Mailing Address:
	Phone:
	FAX:
	E-mail:
☐	I am not now represented by counsel. If and when counsel is retained, immediate notification of the attorney's name, address and telephone number will be filed with the Office of Administrative Hearings and a copy sent to Complainant so that counsel will be on record to receive legal notices, pleadings and other papers.

The agency taking the action described in the Accusation may have formulated disciplinary guidelines to assist the administrative law judge in reaching an appropriate penalty. You may obtain a copy of the guidelines by requesting them in writing from the agency.

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BEFORE THE
BOARD OF REGISTERED NURSING
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SAMANTHA JEANNE PERKINS** Respondent.	Case No. 4002023003518 **NOTICE OF DEFENSE** [Gov. Code §§ 11505 and 11506]

I, the undersigned Respondent in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Accusation; Statement to Respondent; Government Code sections 11507.5, 11507.6 and 11507.7, Complainant's Request for Discovery, and two copies of a Notice of Defense.

Date:	
Respondent's's Name:	
Respondent's's Signature:	
Phone:	
E-mail:	

NOTE: ALL COMMUNICATIONS WILL BE SENT TO YOUR ADDRESS OF RECORD WITH THE BOARD. ANY CHANGES TO YOUR ADDRESS OF RECORD MUST BE MADE DIRECTLY WITH THE BOARD.

Check appropriate boxes:

☐	I hereby request a hearing to permit me to present my defense to the Accusation.
☐	I wish to be considered for a stipulated settlement.
☐	I wish to surrender my license.
☐	I am represented by counsel, whose name, address and telephone number appear below:

	Counsel's Name:
	Counsel's Mailing Address:
	Phone:
	FAX:
	E-mail:
☐	I am not now represented by counsel. If and when counsel is retained, immediate notification of the attorney's name, address and telephone number will be filed with the Office of Administrative Hearings and a copy sent to Complainant so that counsel will be on record to receive legal notices, pleadings and other papers.

The agency taking the action described in the Accusation may have formulated disciplinary guidelines to assist the administrative law judge in reaching an appropriate penalty. You may obtain a copy of the guidelines by requesting them in writing from the agency.

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COPY OF GOVERNMENT CODE SECTIONS 11507.5, 11507.6 AND 11507.7 PROVIDED PURSUANT TO GOVERNMENT CODE SECTIONS 11504 AND 11505

SECTION 11507.5: Exclusivity of discovery provisions

The provisions of Section 11507.6 provide the exclusive right to and method of discovery as to any proceeding governed by this chapter.

SECTION 11507.6: Request for discovery

After initiation of a proceeding in which a respondent or other party is entitled to a hearing on the merits, a party, upon written request made to another party, prior to the hearing and within 30 days after service by the agency of the initial pleading or within 15 days after the service of an additional pleading, is entitled to (1) obtain the names and addresses of witnesses to the extent known to the other party, including, but not limited to, those intended to be called to testify at the hearing, and (2) inspect and make a copy of any of the following in the possession or custody or under the control of the other party:

(a) A statement of a person, other than the respondent, named in the initial administrative pleading, or in any additional pleading, when it is claimed that the act or omission of the respondent as to this person is the basis for the administrative proceeding;

(b) A statement pertaining to the subject matter of the proceeding made by any party to another party or person;

(c) Statements of witnesses then proposed to be called by the party and of other persons having personal knowledge of the acts, omissions or events which are the basis for the proceeding, not included in (a) or (b) above;

(d) All writings, including, but not limited to, reports of mental, physical and blood examinations and things which the party then proposes to offer in evidence;

(e) Any other writing or thing which is relevant and which would be admissible in evidence;

(f) Investigative reports made by or on behalf of the agency or other party pertaining to the subject matter of the proceeding, to the extent that these reports (1) contain the names and addresses of witnesses or of persons having personal knowledge of the acts, omissions or events which are the basis for the proceeding, or (2) reflect matters perceived by the investigator in the course of his or her investigation, or (3) contain or include by attachment any statement or writing described in (a) to (e), inclusive, or summary thereof.

For the purpose of this section, "statements" include written statements by the person signed or otherwise authenticated by him or her, stenographic, mechanical, electrical or other recordings, or transcripts thereof, of oral statements by the person, and written reports or summaries of these oral statements.

Nothing in this section shall authorize the inspection or copying of any writing or thing which is privileged from disclosure by law or otherwise made confidential or protected as the attorney's work product.

SECTION 11507.7: Petition to compel discovery; Order; Sanctions

(a) Any party claiming the party's request for discovery pursuant to Section 11507.6 has not been complied with may serve and file with the administrative law judge a motion to compel discovery, naming as respondent the party refusing or failing to comply with Section 11507.6. The motion shall state facts showing the respondent party failed or refused to comply with Section 11507.6, a description of the matters sought to be discovered, the reason or reasons why the matter is discoverable under that section, that a reasonable and good faith attempt to contact the respondent for an informal resolution of the issue has been made, and the ground or grounds of respondent's refusal so far as known to the moving party.

(b) The motion shall be served upon respondent party and filed within 15 days after the respondent party first evidenced failure or refusal to comply with Section 11507.6 or within 30 days after request was made and the party has failed to reply to the request, or within another time provided by stipulation, whichever period is longer.

(c) The hearing on the motion to compel discovery shall be held within 15 days after the motion is made, or a later time that the administrative law judge may on the judge's own motion for good cause determine. The respondent party shall have the right to serve and file a written answer or other response to the motion before or at the time of the hearing.

(d) Where the matter sought to be discovered is under the custody or control of the respondent party and the respondent party asserts that the matter is not a discoverable matter under the provisions of Section 11507.6, or is privileged against disclosure under those provisions, the administrative law judge may order lodged with it matters provided in subdivision (b) of Section 915 of the Evidence Code and examine the matters in accordance with its provisions.

(e) The administrative law judge shall decide the case on the matters examined in camera, the papers filed by the parties, and such oral argument and additional evidence as the administrative law judge may allow.

(f) Unless otherwise stipulated by the parties, the administrative law judge shall no later than 15 days after the hearing make its order denying or granting the motion. The order shall be in writing setting forth the matters the moving party is entitled to discover under Section 11507.6. A copy of the order shall forthwith be served by mail by the administrative law judge upon the parties. Where the order grants the motion in whole or in part, the order shall not become effective until 10 days after the date the order is served. Where the order denies relief to the moving party, the order shall be effective on the date it is served.

****

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DECLARATION OF SERVICE BY CERTIFIED MAIL AND FIRST CLASS MAIL
(Separate Mailings)

Case Name: **In the Matter of the Accusation Against Samantha Jeanne Perkins**

No.: **4002023003518**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar at which member's direction this service is made. I am 18 years of age or older and not a party to this matter. I am familiar with the business practice at the Office of the Attorney General for collection and processing of correspondence for mailing with the United States Postal Service. In accordance with that practice, correspondence placed in the internal mail collection system at the Office of the Attorney General is deposited with the United States Postal Service with postage thereon fully prepaid that same day in the ordinary course of business.

On December 3, 2024, I served the attached **STATEMENT TO RESPONDENT; ACCUSATION; REQUEST FOR DISCOVERY; NOTICE OF DEFENSE (2 Copies); and GOVERNMENT CODE SECTION 11507.5, 11507.6 and 11507.7** by placing a true copy thereof enclosed in a sealed envelope as certified mail with return receipt requested, and another true copy of the **STATEMENT TO RESPONDENT; ACCUSATION; REQUEST FOR DISCOVERY; NOTICE OF DEFENSE (2 Copies); and GOVERNMENT CODE SECTION 11507.5, 11507.6 and 11507.7** was enclosed in a second sealed envelope as first class mail in the internal mail collection system at the Office of the Attorney General at 600 West Broadway, Suite 1800, P.O. Box 85266, San Diego, CA 92186-5266, addressed as follows:

Derek F. O'Reilly-Jones, Esq.
Bonne Bridges Mueller O'Keefe & Nichols - Los Angeles
355 South Grand Ave., Ste. 1750
Los Angeles, CA 90071-5162
(First Class Mail only)

Samantha Jeanne Perkins
[redacted]

Certified Article Number
9414 7266 9904 2232 2865 47
SENDER'S RECORD

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct and that this declaration was executed on December 3, 2024, at San Diego, California.

H. Tesfagiorgis
Declarant

[redacted]
Signature

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SP [redacted]

You replied to this message on 1/29/2025 11:12 AM.

Both. I will apply for my DEA after you

Get Outlook for iOS

From: [redacted]
Sent: Wednesday, January 29, 2025 11:04:26 AM
To: [redacted]
Subject: RE: BRN Accusation Filed

One more thing. On the application you marked Dangerous Drugs Only which is a $80 fee. You also marked the schedules.

Are you prescribing Dangerous Drugs Only or Both Dangerous Drugs and Controlled Substances?

Rev (01/03/2023)

What types of drug(s) will you be prescribing?
☒ Dangerous Drugs ONLY (**Non-Refundable $80 Fee) (PR)**
☐ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (**Non-Refundable $200 Fee) (CS)**
Select the Controlled Substance Schedules you are applying to prescribe
☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Samantha Middle: Jeanne Last: Perkins

[redacted]

Licensing Specialist
Nevada State Board of Pharmacy
(775) 850-1440 [redacted]

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

SAMANTHA PERKINS

Friday, February 14 2025 02:31:17 PM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PERKINS, SAMANTHA	RN	884504	Inactive	11/06/2024	01/03/2025	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PERKINS, SAMANTHA	RN	884504	Active	01/03/2025	07/14/2026	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
PERKINS, SAMANTHA	APRN-CNP	884504	Active Prescribing - CII	01/03/2025	07/14/2026	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Psychiatric Mental Health
  - Has discipline: NO
  - Expiration Date: 07/14/2026
  - Original Issuance Date: 01/03/2025
  - Current Issue Date: 01/03/2025
  - Certification expiration date: 08/03/2028

License type information

- **RN:** Registered Nurse

12C

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

130592

What types of drug(s) will you be prescribing?

- ☒ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)
- ☐ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)
  Select the Controlled Substance Schedules you are applying to prescribe
  - ☐ Schedule I ☐ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Rebecca Middle: Ann Last: Ballinger

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: [redacted]

Telephone: [redacted] Email: [redacted]

APRN License #: 887104 Specialty: Psychiatric Mental Health Nurse Practitioner

(A **current license and active-PRESCRIBING status** with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: VA Medical Center of Reno

Practice Address: 975 Kirman Avenue Suite #: N/A

City: Reno State: NV Zip: 89502

Telephone: 1-888-838-6256 Fax: N/A Email: [redacted]

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☐ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: _____

Collaborating Physician Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

N

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✓	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

- Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/12/1999	3/24/2000	CA	Nevada City	Nevada County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
F99080	Nevada County Superior Court

Reason/Charge
10980(C)(2) WI - Fraud to obtain aid and 118 PC - Perjury

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

Convictions expunged on March 13, 2009 - Please see attached letter of explanation

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/8/2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/27/2006	12/9/2006	CA	Nevada City	Nevada County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
M06-0360	Nevada County Superior Court

Reason/Charge
11550(a) HS (Under the influence of a controlled substance)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
Conviction deferred on 11/27/2007 - Please see attached letter of explanation

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/8/2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/4/2006	5/21/2007	CA	Nevada City	Nevada County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
M06-1957	Nevada County Superior Court

Reason/Charge
11364(a) HS (Possession of Paraphernalia)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
Conviction set aside and dismissed on 5/27/2008 - Please see attached letter of explanation

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/8/2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/20/2009	9/2/2009	CA	Nevada City	Nevada County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
M09-0582(a)(b)	Nevada County Superior Court

Reason/Charge
1415(2) PC (Loud/unreasonable noise)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
Conviction deferred on 9/2/2009 - Please see attached letter of explanation

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/8/2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	11/6/2013	NV	Reno	Washoe County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
0336-13Y	Nevada Board of Nursing

Reason/Charge
Five-year monitoring agreement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
Successfully completed on 4/26/2019 - Please see attached letter of explanation

[redacted]
Original Signature (electronic, copies or stamps not accepted)

2/8/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rebecca Ballinger

Applicant Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/8/2025

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: 2/11/25 Amount: $80 cc ✓

February 8, 2025

Nevada Board of Pharmacy

Dear Members of the Board of Pharmacy:

My name is Rebecca Ballinger, and I am writing to provide a comprehensive disclosure of my criminal history as part of my application for a prescribing license. I am committed to being open about my past, owning up to my mistakes, and illustrating how I've turned my life around through hard work and dedication.

March 24, 2000: Welfare Fraud and Perjury (10980(C)(2) and 118 PC)
In 1999, as a single mother facing financial hardship, I made the serious error of misrepresenting my financial situation on welfare forms and received a felony conviction for welfare fraud and perjury. I was placed on a 3-year probationary period and ordered to pay restitution. While my circumstances were challenging, I fully acknowledge that my decision to be untruthful was wrong. On March 13, 2009, these charges were expunged under Penal Code 1203.4, though I understand my ongoing obligation to disclose them for the purpose of licensure.

December 9, 2006: 11550(a) HS; May 21, 2007: 11364(a) HS and 1320(a) PC
Between 2006 and 2007, I experienced a period of personal struggle with methamphetamine, which led to several misdemeanor charges. In 2006, I received a conviction for being under the influence of a controlled substance. In 2007, I was charged with possession of drug paraphernalia. During the 2007 case, I accumulated two failure-to-appear convictions due to my ongoing substance use affecting my judgment and reliability. While these charges were later dismissed after completing court-ordered drug treatment, I take full responsibility for my actions during this period.

April 20, 2009: 415(2) PC
In 2009, I received a charge of noise violation, which was later dismissed on 9/2/2009. While alcohol wasn't mentioned in the official charge, I acknowledge that it was a contributing factor in the event.

These incidents represent a difficult period in my life when substance use was negatively impacting my decision-making and behavior. While the charges were ultimately deferred or expunged, they served as the catalyst for profound personal change. I recognized that I needed help and took decisive action to transform my life.

My last interaction with the criminal justice system was in 2009. Recognizing my need for support, I committed to a voluntary intensive outpatient treatment program from October 2010 to March 2011. October 1st, 2010, became my true north—the day I began my journey to sustained recovery. Through committed work in treatment, therapy, and recovery programs, I've built both effective coping skills and a strong support network. These experiences shaped my career path in a meaningful way. Having experienced firsthand both the struggle of substance use disorder and the life-changing impact of proper treatment and support, I chose to dedicate my professional life to helping others facing similar challenges.

November 6, 2013: Case 0336-13Y (Nevada Nursing Board Monitoring Agreement)
In 2013, I disclosed my history to the Nevada Board of Nursing when applying for my RN license. After initial denial and appropriate due process, the Board granted my license under a five-year monitoring agreement. I completed my monitoring agreement, without violations, in April of 2019. This successful monitoring period demonstrated my commitment to rehabilitation and professional excellence. I have maintained an unblemished nursing record for approximately 10 years. My professional standing was further affirmed in June 2020, when I obtained RN licensure (95223304) through California's stringent review process. While I no longer maintain active status in California, successfully meeting their exacting standards provides additional testament to my record of professional conduct.

In April 2020, I secured employment as a federal RN at the VA Medical Center of Reno, working on a high-intensity mental health unit. This role revealed my true calling and strengthened my commitment to helping those with mental health and substance use disorders. My passion led me to pursue advanced training as a Psychiatric Mental Health Nurse Practitioner (PMHNP), culminating in my licensure on February 4th, 2025. The Nevada Board of Nursing's decision to grant me full, unrestricted APRN licensure affirms their trust in my rehabilitation and professional integrity.

My professional journey has culminated in my selection for the highly competitive PMHNP Residency program at the VA Medical Center, which I began on January 27, 2025. In this role, I combine my clinical expertise with lived experience to serve Veterans facing mental health and substance use challenges – a mission that mirrors my own path from struggle to recovery to service.

My experiences have uniquely prepared me to understand and support those struggling with mental health and substance use challenges. As a PMHNP, I can now provide the kind of comprehensive, empathetic care that I know firsthand is essential for recovery. My residency at the VA Medical Center allows me to combine clinical expertise and personal insight to provide therapeutic and effective care.

I fully appreciate the Board's fundamental responsibility to protect public safety and maintain the integrity of pharmaceutical practice. My path of sustained recovery and professional development demonstrates an unwavering commitment to these essential standards. The Nevada Board of Nursing's decision to grant me an unrestricted nurse practitioner licensure validated my dedication to ethical practice. My current position at the VA Medical Center, serving our nation's Veterans, represents the continuation of this commitment to exemplary practice standards.

I respectfully ask the Board to consider my application, based on my demonstrated rehabilitation, professional accomplishments, and commitment to safe patient care. I am willing to provide any additional information that would assist in your review.

Sincerely,

[redacted]

Rebecca Ballinger, MSN, APRN, PMHNP-BC

KAMALA D. HARRIS
Attorney General

State of California
DEPARTMENT OF JUSTICE

BUREAU OF CRIMINAL INFORMATION AND ANALYSIS
P.O. Box 903417
SACRAMENTO, CA 94203-4170

April 19, 2011

REBECCA ANN BALLINGER
[redacted]

RE: California Criminal History Information

Dear Applicant:

This is in response to your record review request concerning the existence of a California criminal history record maintained in the files of the Department of Justice's Bureau of Criminal Information and Analysis. Your fingerprints did identify to an existing California criminal history record and a copy of that record is enclosed. If you wish to challenge the accuracy or completeness of your record, please complete and return the enclosed form (BCIA 8706) and supporting documentation to the address noted above.

Pursuant to California Penal Code section 11121, the purpose of a record review request is to afford an individual with a copy of their record and to refute any erroneous or inaccurate information contained therein. The intent is not to be used for licensing, certification or employment purposes.

Additionally, California Penal Code sections 11125, 11142, and 11143 does not allow for a person or agency to make a request to another person to provide them with a copy of an individual's criminal history or notification that a record does not exist; does not allow an authorized person to furnish the record to an unauthorized person; nor does it allow an unauthorized person to buy, receive or possess the record or information. A violation of these section codes is a misdemeanor.

Sincerely,

[redacted]

KEITH DANN, Manager
Record Access & Security Program
Bureau of Criminal Information and Analysis

For KAMALA D. HARRIS
Attorney General

Enclosures
BCIA 8711 (Rev. 06/10)

RE: QHY.CA0349400.20182582.S DATE:20110419 TIME:16:06:15
RESTRICTED-DO NOT USE FOR EMPLOYMENT,LICENSING OR CERTIFICATION PURPOSES
ATTN:S

****

FOR CALIFORNIA AGENCIES ONLY - HAS PREVIOUS QUALIFYING

OFFENSE. COLLECT DNA IF INCARCERATED, CONFINED, OR ON

PROBATION OR PAROLE FOLLOWING ANY MISDEMEANOR OR FELONY
CONVICTION. REQUEST KITS AND INFO AT (510) 620-3300 OR
PC296.PC296@DOJ.CA.GOV.
****
III CALIFORNIA ONLY SOURCE RECORD
CII/A20182582
[redacted]

NAM/01 BALLINGER,REBECCA ANN
02 BALLINGER,REBECCA ANN X
03 GAYMAN,REBECCA ANN X
04 GUEMANN,REBECCA ANN X
05 GAYMAN,REBECCA ANN
06 GUEMANN,REBECCA ANN
07 GAYMAN,REBECCA
08 GUEMANN,REBECCA

FBI/366817KB1
CDL/B6135220
[redacted]
OCC/STUDENT; HOUSE CLEANER
* * * *

ARR/DET/CITE: NAM:01 [redacted]
19990412 CASO NEVADA CITY

CNT:01 #100828
-BOOK/RELEASE
10980(C)(2) WI-FRAUD TO OBTAIN AID TOC:F
CITE #F99080

CNT:02
-BOOK/RELEASE
118 PC-PERJURY TOC:F
CITE #E99080
COM: PHOTO AVAILABLE
COM: SCN-08191020003
- - - -
COURT: NAM:01
20000324 CASC NEVADA CITY

CNT:01 #SF99080
118 PC-PERJURY TOC:F
*DISPO:CONVICTED
CONV STATUS:MISDEMEANOR PER 17PC

CNT:02
10980(C)(2) WI-FRAUD TO OBTAIN AID TOC:F
*DISPO:CONVICTED
CONV STATUS:MISDEMEANOR PER 17PC
SEN: 3 YEARS PROBATION, 31 DAYS JAIL,
30 DAYS JAIL SS, FINE,
WORK PROGRAM
COM: :

CORRECTED COPY

20040922
DISPO:CHRGS&DIRECT CONSEQUENCES OF PLEA
DISPO:DEFENDANT REPRESENTED BY COUNSEL
DISPO:RIGHT TO TRIAL BY JURY WAIVED-YES
DISPO:PRIV AGNST COMPLSRY SLF INCRIM&WAIVE-YES
DISPO:RIGHT CONFRONT&CROSS EXAM WIT&WAIVE-YES
DISPO:DEF COUNSEL CONCURRED DEFNDT. PLEA/ADMISS
DISPO:CRT FIND PLEA KNOWLDGE&INTELLIGNT&VOLUNT

20040922
DISPO:CONVICTION CERT BY CLERK OF THE COURT
COM: CONVICTION CERTIFIED BY KAREN DRISCOLL, CLERK, CASCNEVADA

20090323
DISPO:CONV SET ASIDE & DISM PER 1203.4 PC
* * * *

ARR/DET/CITE: NAM:02 [redacted]
20060129 CASO NEVADA CITY

CNT:01 #134719-100828
11550 HS-USE/UNDER INFLUENCE CONTROL SUBST TOC:M
[redacted]
COM: PHOTO AVAILABLE
COM: SCN-08160290007
- - - -
COURT: NAM:02
20060523 CASC NEVADA CITY

CNT:01 #M06 0360
11550(A) HS-USE/UNDER INFL CONTRLD SUBSTANCE TOC:M
DISPO:PROC SUSP/DRUG CRT-DEFERRED JUDGEMENT
- - - -
COURT: NAM:02
20071127 CASC NEVADA CITY

CNT:01 #M06-0360
11550(A) HS-USE/UNDER INFL CONTRLD SUBSTANCE TOC:M
DISPO:DRUG CRT-DEFERRED JDGMNT TERM-SUCCESSFUL
* * * *

ARR/DET/CITE: NAM:01 [redacted]
20070502 CASO NEVADA CITY

CNT:01 #141972
-COURT REMAND
11364 HS-POSSESS CONTROL SUBSTANCE PARAPHERNA TOC:M

CNT:02
-COURT REMAND
1320(A) PC-FAIL APPEAR:MISDEMEANOR CHARGE TOC:M
COM: ADR-20070502 (210, SUTTON, 225,, GRASS VALLEY, CA, 95945)
COM: PHOTO AVAILABLE
COM: SCN-08171220003
- - - -
COURT: NAM:01
20070521 CASC NEVADA CITY

CNT:01 #M061957

1320(A) PC-FAIL APPEAR:MISDEMEANOR CHARGE TOC:M
DISPO:DISMISSED/FURTHERANCE OF JUSTICE

CNT:02
11364 HS-POSSESS CONTROL SUBSTANCE PARAPHERNA TOC:M
*DISPO:CONVICTED
CONV STATUS:MISDEMEANOR

CNT:03
1320(A) PC-FAIL APPEAR:MISDEMEANOR CHARGE TOC:M
*DISPO:CONVICTED
CONV STATUS:MISDEMEANOR
SEN: 36 MONTHS PROBATION, FINE

DISPO:COND OF PROB-DRUG TREATMENT PLACEMENT
DISPO:CONVICTION CERT BY CLERK OF THE COURT
DISPO:FOR CERT INFO SEE AUTOMATED ARCHIVE SYS

20080527
.DISPO:CONV SET ASIDE & DISM PER 1210.1(E)(1)PC
* * * *

APPLICANT: NAM:01
20081008 CASD SOCIAL SERV CCL-CRCB, SACRAMENTO

CNT:01 #297001933
APPLICANT RESIDNTL CARE FACILITY FOR ELDERLY
COM: SCN-080B2820011 ATI-M282BAR012

20090623
DISPO:NO LONGER INTERESTED
COM: ACN-DSS917001280030000000000000000
* * * *

ARR/DET/CITE: NAM:01 DOB:19771229
20090420 CAPD GRASS VALLEY

CNT:01 #152314-100828
415(2) PC-DISTURBS BY LOUD/UNREASONABLE NOISE TOC:M
ARR BY:CASO NEVADA CITY
COM: PHOTO AVAILABLE
COM: SCN-081C1110006
- - - -
COURT: NAM:01
20090902 CASC NEVADA CITY

CNT:01 #M090582A
415(2) PC-DISTURBS BY LOUD/UNREASONABLE NOISE TOC:M
DISPO:DRUG CRT-DEFERRED JDGMNT TERM-SUCCESSFUL
* * * END OF MESSAGE * * *

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF NEVADA

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

vs.

REBECCA ANN BALLINGER,
aka REBECCA ANN GAYMAN,
aka REBECCA ANN GUEMANN,

[redacted]

Defendant(s).

INFORMATION

NO.: SF99-080

COUNT I

The District Attorney of the County of Nevada, State of California, hereby accuses **Rebecca Ann Ballinger, aka Rebecca Ann Gayman, aka Rebecca Ann Guemann** of a Felony, to wit: violation of **section 10980(C)(2) of the Welfare and Institutions Code** of the State of California, in that on or about and between **June 01, 1998 through and including the date of February 28, 1999**, in the County of Nevada, State of California, said defendant(s) did then and there, willfully, unlawfully and feloniously and by means of false statements, representations, impersonation, or other fraudulent device, obtain and retain aid for a child to wit: **Christian McGrath, date of birth 07-24-98**, not in fact entitled thereto, in excess of Four Hundred Dollars ($400.00)

COUNT II

The District Attorney of the County of Nevada, State of California, hereby further accuses **Rebecca Ann Ballinger, aka Rebecca Ann Gayman, aka Rebecca Ann Guemann** of a Felony, to wit: violation of **section 118 of the Penal Code** of the State of California, in that on or about and between **July 01, 1998, through and including the date of January 31, 1999** in the County of Nevada, State of California, said defendant(s) did then and there, willfully, unlawfully and feloniously being a person who testified, declared and deposed, and certified under oath and under penalty of perjury on an application for aid and medical assistance provided for in Welfare and Institutions Code Section 11054 that said defendant(s) and applicant(s) met the specific conditions of eligibility for said aid and medical assistance, did willfully, knowingly, and with intent to deceive, state as true on said application and in response to said inquiry, a material matter which said defendant(s) knew to be false, to wit: that defendant(s) possessed no monetary resources which were not reported, when in fact she did possess such resources, and did state she did not reside with any other adult, which she knew to be false.

Dated on this 18 day of June, 1999 at Nevada City, Nevada County, California.

MICHAEL W. FERGUSON, District Attorney

By: _____
James P. Phillips
Deputy District Attorney

DA#179736
\sh

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF NEVADA

Date : 03/24/00

Case No.: SF99-080

Judge: M. KATHLEEN BUTZ

Reporter: BONNIE REKERS

Clerk: KAREN DRISCOLL

Bailiff : JUDY COSTELLO

The People Vs.
BALLINGER, REBECCA ANN

Counsel : DISTRICT ATTORNEY
Counsel : MUNKELT, STEPHEN

Charges:
1. 10980(c)(2) WI
2. 118 PC

NATURE OF PROCEEDINGS: MOTION - NEW TRIAL; SENTENCING COUNTS 1, 2

APPEARANCES: KRISTIN HACKLER, DDA; STEPHEN MUNKELT/DEFENDANT

DEFENDANT'S REPLY BRIEF IS FILED. THE COURT HAS READ AND REVIEWED ALL OF THE DOCUMENTS ON FILE AS WELL AS CITED CASES. FOLLOWING ADDITIONAL ORAL ARGUMENTS THE COURT DENIES THE MOTION FOR NEW TRIAL AND THE MATTER IS CONTINUED TO 1:30 PM FOR SENTENCING.

[X] The court has read and reviewed all reports and documents submitted. Defendant waives further arraignment for sentencing. There being no legal cause why sentence should not now be imposed, DEFENDANT IS SENTENCED AS FOLLOWS:

Rendition of judgment and imposition of sentence is suspended. Defendant is admitted to probation for 3 years from today under the terms and conditions listed on the the probation orders signed this date, including:
31 DAYS NEVADA CO JAIL, 30 SUSPENDED UPON SUCCESSFUL COMPLETION OF 300 HOURS COMMUNITY SERVICE AS DIRECTED BY PROBATION. CREDITS: 1 ACTUAL DAY.

FOLLOWING ARGUMENTS THE COURT GRANTS DEFENDANT'S MOTION TO STAY PERFORMANCE OF COMMUNITY SERVICE AND PAYMENT OF RESTITUTION PENDING OUTCOME OF APPEAL.

CC: DA PROB

COUNTY SUPERIOR COURT
☐ 201 Church St., Nevada City, CA 95959 (530)265-1311
☐ 10075 Levon Ave., Truckee, CA 96161 (530)582-7835

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiffs,

PROBATION ORDER

vs.

CASE NO. SF99-080

PROBATION NO. A990270

BALLINGER, REBECCA ANN, Defendant.

CONVICTED OF: Ct. 1: 10980(c)(2) W&I, felony; Ct.II: 118 PC, a felony

THE COURT ENTERS FOLLOWING ORDERS & CONDITIONS:

☒ SUSPENDS IMPOSITION of sentence and grants the defendant:
☐ Conditional Probation ☒ Supervised Probation

☐ Sentences the defendant to _____ and SUSPENDS EXECUTION of sentence, granting defendant:
☐ Conditional Probation ☐ Supervised Probation

TERM: _____ years from date of this order.

☐ **Modifies/Reinstates Probation:** Original terms in full force and effect, except as amended herein.
New probation termination date: _____

I. GENERAL CONDITIONS

Conditional Probation: OBEY ALL LAWS. Must advise court of any change of address during period of probation.

Supervised Probation:
1. Probationer shall be under the supervision and control of the Probation Officer of Nevada County and shall obey all reasonable and proper instructions given by said Probation Officer.
2. Probationer shall, during the term of this probation, report in person to the Probation Officer once each month, unless said probationer is directed by the Probation Officer to report in some other manner.
3. Probationer shall seek employment or schooling and, as far as possible, remain employed during the term of this probation.
4. Probationer shall, at all times hereunder, uphold and obey the laws of the State of California, and of the United States and the statutes and ordinances of all cities and localities wherein he/she may reside. (The Federal Gun Law of 1968 prohibits any person convicted of a felony the use or possession of a handgun, rifle, or shotgun).
5. Probationer shall not leave this State without first securing written permission from the Probation Officer and is further required to immediately advise the Probation Officer at least 48 hours in advance of his/her current residence and of any change in such residence.

II. SERVE JAIL AS FOLLOWS

☒ 120 days in the NEVADA COUNTY JAIL with 1 days CREDIT FOR TIME SERVED
COMMENCING: _____ @ _____

☐ Jail sentence is consecutive/concurrent to _____

Report date _____ and time _____, unless an application for a Sheriff's Department Alternative Sentencing Program has been accepted prior to report date. Probationer to comply with all terms and conditions of program.

☐ Not eligible for Alternative Sentencing Program except _____.

☐ _____ days shall be suspended on conditions of no VOP's and _____

☐ _____ days to be served on Work Release Program
(Report to Probation Department to apply for program and pay applicable fees.)

III. RESTITUTION ORDERS AS FOLLOWS

☒ RESTITUTION SET IN THE AMOUNT OF
$ 4,648.00
☐ By stipulation, defendant understands rights and waives hearing.
☐ Determined by court at hearing.
☐ Court reserves right to order restitution following notice and hearing.
☐ Hearing Set for _____ at _____.
PAYMENT OF RESTITUTION (*with costs) SHALL BE AS FOLLOWS:
☐ Collections Dept., Courthouse, Nevada City, CA 95959
☒ (W&I case):DPSS: Collections, PO Box 1210, Nevada City, CA 95959
*If defendant disagrees with costs, he/she may have court hearing regarding costs.
☐ in full on or before _____.
☐ in installments of $_____ per month beginning _____.
☐ as determined by Collections/Probation Dept. based on ability to pay.

IV. PAY FINES/FEES AS FOLLOWS

$ 540.00 Fine & PA: $_____
$ (_____) Suspended on condition _____
$ 200.00 Victim Restitution Fund Fine [PC§1202.4]
$_____ OR/Cite Fee [GC§29550]
$_____ Installment Account Fee [PC§1205(d)]
$_____ Domestic Violence Fine [PC§1203.097(a)(5)]
$_____ **Women's Shelter [PC§1203.097(a)(11)(A)]
$_____ Crime Prevention Fine [PC§1202.5(a)] (includes PA)
$_____ Criminal Lab Fee [H&S§11372.5(a)] (includes PA)
$_____ Drug Program Fee [H&S§11372.7]
$_____ Aids Education Testing Fee [B&P§4583.4/H&S§11550(d)]
$_____ Sexual Habitual Offender Fund [PC§290.3]
$_____ Fish & Game Preservation Fund [F&G§12021]
$_____ **Drug testing fee [PC§1203.1ab]. **Pay to Collections

*$_____ TOTAL DUE: PAYABLE AS FOLLOWS:
☐ in installments of $_____ per month beginning _____.
☐ in full on or before _____.
☐ _____ hours community service lieu of fine due by _____
☐ Jail in lieu of fine: credited @ $_____/day, consecutive to jail above.
☐ Fine converted to _____ hours community service. Proof to the Court by _____
☐ Pay to Court ☒ Pay to Collections, Courthouse, Nevada City, CA 95959
*Failure to pay may result in additional assessment and referral to collection agency.

V. SUBSTANCE ABUSE OFFENSE CONDITIONS

A. ☐ You shall not possess/consume controlled substances and you shall notify court/probation dept. within 72 hours of any controlled substance prescribed to you by a physician. Submit to chemical testing of blood/breath/urine for the detection of drugs at the request of a peace officer or probation officer. Type of test at the officer's discretion.

B. ☐ Attend Drug Counseling as follows: _____ or as directed by Probation Officer.

C. ☐ Notice is Given:
☐ 12 month driver's license suspension per CVC §13202.3/13202.5
☐ Restricted license granted as compelling circumstances exist.
☐ You are ineligible for aid per W&I§11251.3 and county shall issue rent vouchers for remaining eligible family members.

VI. DUI/ALCOHOL/DRIVERS LICENSE CONDITIONS

A. ☐ Shall not drive unless licensed and insured and shall not drive with a measurable amount of alcohol in your body.

B. ☐ License: ☐ suspended ☐ revoked for _____ months/years

C. ☐ License restricted for 90 days ☐ 24 mths ☐ 30 mths ☐
If 90 days, it is consecutive to DMV Admin per se suspension. If 24/30 months, per SB 330/38 you must enroll in 2nd offender program and not drive until DMV reinstates your license and then follow DMV restrictions.

D. ☐ You are declared a habitual traffic offender for _____ years.

[redacted]LLINGER, REBECCA ANN

CASE NO. SF99-080

E. ☐ Must enroll/attend/complete alcohol program at Nev[redacted]ounty Substance Abuse or in _____ *County[redacted]e per terms of referral delivered to defendant in court for the following program:
☐ 1st Offender ☐ 3 months ☐ 6 months
☐ 9 months ☐ 12 months
☐ 2nd Offender ☐ 18 months ☐ 30 month
☐ 12 hour educational
*Proof of Enrollment due by _____
*Proof of Completion due by _____

F. ☐ Attend _____ AA meetings or _____ meetings per week and show proof to court/probation by _____.

G. ☐ Submit to chemical testing of blood/breath/urine for the detection of alcohol at the request of a peace/prob. officer. Type of test at the officer's discretion.

H. ☐ You shall not consume or possess alcoholic beverages or enter places where alcoholic beverages are served/sold as primary source of income.

I. ☐ _____ hours of community service. Proof due by _____.

J. ☐ Ignition Interlock Order issued and filed.

VII. DOMESTIC VIOLENCE CONDITIONS

A. ☐ You shall complete a Batterer's Program per PC§1203.097. You must enroll within 10 days.
Proof of enrollment due _____.
Program shall be not less than: _____years.

B. ☐ You shall not annoy/harass/strike the victim(s) _____
_____
You shall not ☐contact, and ☐shall stay _____ yards away from victim(s), _____, his/her residence and place of employment.
☐ Dwelling Exclusion Applicable. ☐ _____

C. ☐ You shall perform _____ hours of community service and show proof of completion to court/probation by _____.

VIII. REGISTRATION REQUIREMENTS

You shall register as a:
☐ Controlled Substances Offender H&S§11590
☐ Sex Offender PC§290
☐ Arson Offender PC§457.1

IX. OTHER CONDITIONS

A. ☐ You shall submit your person/residence/vehicle/personal property to search and seizure by any peace officer or probation officer at any time, day or night, with or without a warrant and with or without reasonable or probable cause.

B. ☐ You shall participate in counseling for _____ and not discontinue without consent of therapist/court/probation officer.

C. ☐ You shall not possess, use, or have under your control any firearm/dangerous weapon. PC§12020.

D. ☐ Other: _____

X. OTHER COSTS

A-C NOT A TERM OF PROBATION, Collectable by Civil Judgment

A. ☐ Pay such collections fees authorized by Nevada County Ordinances and/or the Penal Code.

B. ☐ Pay $300 / $125 for the cost of presentence report.

C. ☐ Pay $25.00 per month for monthly probation supervision until termination of probation or order of this court.
*Pay A-C through Collections Dept., Courthouse, Nevada City, CA 95959

D. ☐ Pay $_____ booking fee per GC§29550.1 to _____.

E. ☐ Other: _____.

XI. NOTICES

You can petition under PC§1203.4 for an order vacating your plea and entry of order of dismissal upon successful completion of probation.

If you possess or have under your custody or control any firearm within 10 years of conviction, you are guilty of a misdemeanor. This notice applies to convictions of PC Sections 71, 76, 136.5, 140, 148(d), 171b, 171c, 171d, 186.28, 240-243, 244.5, 245, 245.5, 246, 246.3, 247, 273.5, 273.6, 417, 417.1, 417.2, 417.6, 626.9, 646.9, 12023, 12024, 12034(b)(d), 12040, 12072(g)(3), 12072(b) and W&I Sections 12100(a), 12220, 12320, 12590 871.5, 1001.5, 8100, 8101 and 8103.

DONE IN OPEN COURT ON: _____

_____
JUDGE OF THE NEVADA COUNTY SUPERIOR COURT

I UNDERSTAND, ACCEPT AND AGREE TO ABIDE BY THE ABOVE CONDITIONS OF PROBATION WHICH I HAVE READ AND RECEIVED. I WAIVE EXTRADITION IN THE EVENT I LEAVE THE STATE OF CALIFORNIA DURING TERM HEREOF.

_____
DEFENDANT SIGNATURE

_____
Mailing Address

_____
City/State Phone Number

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF NEVADA

Date : 03/13/09 | Case No.: SF99-080

Judge: ROBERT L. TAMIETTI | Reporter: PENNY GORDON

Clerk: | Bailiff : JEFF TYNER

The People Vs. | Counsel : DISTRICT ATTORNEY
BALLINGER, REBECCA ANN | Counsel : MUNKELT, STEPHEN

Charges:
1. 10980(c)(2) WI
2. 118 PC

NATURE OF PROCEEDINGS: 1203.4 PC PETITION

APPEARANCES: DDA KENNETH TRIBBY; DEFENDANT

NO OPPOSITION BY THE PEOPLE. MOTION GRANTED, DEFENDANT'S PLEA IS HEREBY WITHDRAWN CASE DISMISSED PURSUANT TO 1203.4 PC.

CC: DA PROB

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF NEVADA

FILED
NEVADA COUNTY
06 FEB 24 PM 1:48
SUPERIOR COURT
DEPUTY

THE PEOPLE OF THE STATE OF CALIFORNIA,	**NO.: M06-0360**
Plaintiff,	**MISDEMEANOR COMPLAINT**
vs.	
REBECCA ANN BALLINGER, [redacted]	
Defendant.	

6 1000.0

COUNT I

The undersigned hereby declares, upon information and belief, based upon the declaration filed herewith, that defendant, did in the said County of Nevada, State of California, on or about **January 27, 2006,** commit a violation of **Section 11550(a) of the Health and Safety Code** of the State of California, a misdemeanor, in that said defendant did then and there, willfully and unlawfully use and be under the influence of a controlled substance.

NOTICE: Conviction of this offense will require you to register pursuant to Health & Safety Code section 11590. Failure to do so is a crime pursuant to Health and Safety Code section 11594.

Said complainant therefore prays, based upon the complaint and declaration, that a warrant may be issued for the arrest of the defendant who may then be dealt with according to law.

I declare under penalty of perjury, and upon information and belief, based upon the declaration filed therewith, that the foregoing is true and correct.

Executed at Nevada City, Nevada County, California, on this 24 day of February, 2006.

MICHAEL W. FERGUSON, District Attorney

By: _____
Kenneth M. Tribby
Deputy District Attorney

/kbi
DA#211593

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

REBECCA ANN BALLINGER [NCSBN ID: 22427800]

Friday, February 14 2025 02:22:59 PM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BALLINGER, REBECCA ANN	RN	RN77733	Active	12/24/2013	12/29/2025	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BALLINGER, REBECCA ANN	APRN-CNP	887104	Active - Prescribing	02/04/2025	12/29/2025	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Psychiatric Mental Health
  - Has discipline: NO
  - Expiration Date: 12/29/2025
  - Original Issuance Date: 02/04/2025
  - Current Issue Date: 02/04/2025
  - Certification expiration date: 01/08/2030

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

Superior Court, Nevada County

THE PEOPLE OF THE STATE OF CALIFORNIA,
-vs.-
REBECCA ANN BALLINGER
[redacted]
DL: Defendant

Criminal Docket # M06-0360

Date AW Issued	Bail Set	Returned
Date BW Issued	Bail Set	Returned
FTPF/VOP W.	Bail Set	Returned

DATE	JUDGE	PROCEEDINGS
2/24/06		COMPLAINT FILED, charging Defendant with having committed on or about 1/27/06 GVPD a MISDEMEANOR/~~FELONY~~, to wit, a violation of Section(s): 11550(a) H&S AMENDED COMPLAINT FILED _____ charging _____
		1. APPEARANCE BY ATTORNEY ___ Special/general appearance made by Attorney _____ ___ Appointed/Retained ___ DDA _____ present. Interpreter _____ ___ Complaint read. ___ Waives reading of complaint and advisement of rights. ___ Plea of _____ entered, see #_____. ___ Matter continued at Attorney's request to _____. ☐OR/BB Continued ☐Commit to SO.$_____
FEB 27 2006	ELE	2. ALL DEFENDANTS IN COURT ADVISED EN BANC AS FOLLOWS: ✓ Right to counsel at all proceedings. ✓ Right to Public Defender if unable to hire private attorney. ✓ Right to speedy trial within 30/45 days or case may be dismissed. ___ Right to preliminary examination within 10/60 court days. ___ Right to trial in Superior Court within 60 days of a holding. ✓ Affect of waiver of right to speedy trial. ✓ Right to trial by judge or by jury. ✓ Right to subpoena witnesses. ✓ Right to confront and cross-examine witnesses. ✓ Right to be a witness in own behalf. ✓ Right against self-incrimination. ✓ Right to represent ~~himself~~herself. ✓ Right of indigent to have court reporter and transcript at no cost. ___ Attorney affirms defendant has been duly arraigned and advised. ___ Court finds probable cause exists for the Warrantless arrest. ___ All Purpose Assignment to Judge _____
FEB 27 2006	ELE)	3. DEFENDANT'S CASE CALLED: (First Appearance for Arraignment) ✓ DDA PONG present. PD DEFENER present. ___ Defendant in custody. ✓ Defendant appears in propria persona/~~with counsel~~ _____ ___ INTERPRETER _____ ☐ Certified ☐ Provisionally qualified, diligent search having been made. ✓ Defendant answers to true name as charged. ✓ Complaint read/~~Defendant/Attorney waives reading~~. ___ Defendant handed copy of felony complaint. ✓ Elements of charge(s) and defenses thereto explained by Court. ✓ Possible punishments explained by Court to Defendant. ___ Enhancement penalties explained to Defendant. ✓ First offense minimum and maximum penalties explained. ___ Second offense minimum and maximum penalties explained. ___ Third offense minimum and maximum penalties explained. ___ Fourth offense minimum and maximum penalties explained. ___ Defendant under 21 years - advised pursuant to Section 13202.5 CVC. ___ Defendant advised of possible punishments on plea of guilty to 23103.5 ___ Defendant self-surrenders on warrant/arrested on warrant. ___ Warrant Recalled ___ DMV Hold Lifted ___ Rights applicable to Extradition explained; ☐ Waived ✓ Defendant says ~~he~~/she heard and understands ~~his~~/her rights. ✓ Defendant requests the Public Defender. ✓ $25 fee ordered. Due by FORTHWITH ___ Application for Appointment of Attorney _____ ___ Defendant says he/she has counsel/wants continuance to seek counsel. ✓ Defendant does/ ~~does not~~ qualify for services of Public Defender ___ Conflict attorney _____ appointed. ___ Defendant referred to Collections Dept. to determine ability to reimburse county for court appointed attorney fees. ✓ Defendant advised ~~he~~/she may have to reimburse County for the Public Defender. ___ Defendant waives right to counsel. ___ Defendant says he/she wishes to pleads Guilty/Not Guilty/Nolo Contendere. ___ For plea see Section # ✓ Matter continued to 03-27-06@ 1:00 P.M. for Appearance of Counsel + entry of plea. ___ Own recognizance release signed/OR continued/BB continued. ___ Commitment to SO. Bail set at $_____ ___ Defendant ordered booked by _____ ___ Discovery to Counsel.
		4. IF CONTINUANCE REQUESTED AND GRANTED ON FIRST APPEARANCE, THE FOLLOWING PROCEEDINGS WERE HAD ON SECOND APPEARANCE: ___ Defendant in custody. ___ Defendant appears in propria persona/with counsel _____ ___ DDA _____ present. Interpreter _____ ___ Defendant re-advised of all rights listed in #2 above ___ Waives further reading of the complaint and advisement of rights. ___ Defendant requests the Public Defender. ___ Defendant does/does not qualify for services of the Public Defender. ___ DEFENDANT WAIVES RIGHT TO COUNSEL. ___ Defendant advised of elements and defenses. ___ Defendant re-advised of penalties. ___ Defendant says he/she understands charge and his/her rights in Court. ___ Matter continued at Defendant's request to _____. ___ Defendant advised total of his requested continued days will be subtracted in determining a speedy trial date. ___ Defendant indicated desire to plead _____. See #_____ for plea. ___ OR/BB to continue. ___ Commitment to S.O., Bail $_____
5/23/06	CBB	5. PRIOR TO ENTRY OF GUILTY PLEA OR NOLO PLEA, DEFENDANT WAIVED THE FOLLOWING RIGHTS: * See Reverse * ✓ Appears ~~in propria persona~~/with counsel Ron Large DDA Tribbey present. ___ INTERPRETER _____ ☐ Certified ☐ Provisionally qualified, diligent search having been made. ___ Defendant admits prior conviction (Date of prior _____, _____, 3 _____) ___ Defendant admits enhancements. ✓ Elements of offense and minimum and maximum punishments explained. See # 3 above. See plea and penalty form attached ✓ DEFENDANT WAIVES RIGHT TO COUNSEL. ✓ DEFENDANT WAIVES RIGHT TO CONFRONT AND CROSS-EXAMINE WITNESSES AGAINST HIM/HER. ✓ DEFENDANT WAIVES RIGHT TO JURY TRIAL. ✓ DEFENDANT WAIVES RIGHT AGAINST SELF-INCRIMINATION. PD advised: ___ ✓ Affect of Nolo Contendere plea explained. ✓ Defendant pleads Guilty to Ct. 1 - pursuant to ~~Section~~ DEJ ✓ Court finds plea and waiver to be freely, voluntarily, intelligently, and expressly made and finds a factual basis for plea. ___ Defendant referred to Probation Dept./Behavioral Health for preparation of a pre-sentence report/assessment. Report and sentencing set for _____ at _____ a.m./p.m. ___ Defendant placed on Summary Court/Supervised Probation for _____ mths/years. See attached Probation Order cc: DA __ PROB. __ ___ Defendant sentenced to pay a fine of $_____ at $_____ per month beginning _____ or $_____ fine converted to jail. ___ Defendant ordered to pay Restitution Fund fine in the amount of $_____ by _____/add to fine payments. ___ Defendant sentenced to serve _____ days in jail, _____ days in work release: Commitment issued to jail/work release to Probation Dept. ✓ DEJ REFERRAL ☐PROP 36 REFERRAL ☐BATTERER'S PROGRAM ☐IN-PATIENT/OUT-PATIENT PROGRAM ✓ Review Date: 11/28/06 @ 8:30 for current 11/28/06 @ 8:30 for demo rev. 11/27/07 @ 8:30 for 18mo. rev. ___ All actions taken by DMV as a result of this offense are presumed valid and are not affected by the Court's Order. ___ OR/BB to continue ___ BB exonerated ___ Commitment to S.O. _____ A/R _____ DMV _____ JUS8715
4-10-06	RLT	6. ENTRY OF NOT GUILTY PLEA ✓ Plea of not guilty entered. ___ Defendant waives 10/60 day Rule for Preliminary Examination; ___ All join in defendant's time waiver. ___ Defendant denies conviction. ___ Defendant denies enhancements. ✓ DEFENDANT WAIVES A JURY TRIAL. ☐NO TIME WAIVER ✓ Defendant waives time for trial/~~preliminary examination~~. ___ Trial/Preliminary Examination set for _____ at _____ a.m./p.m. ___ Trial Readiness Conference/felony Conference set for _____ at _____ a.m./p.m. ✓ Motion 1538.5 Motion Set for 5-16-06 at 9:00 AM ☐Denied ☐Granted ___ OR/BB to continue ___ Commitment to S.O., Bail set $_____
5/23/06	CBB	7. CHANGE OF PLEA ✓ Defendant appears ~~in propria persona~~/with counsel Ron Large ; Interpreter _____ ✓ Motion made to withdraw plea of NOT GUILTY. ✓ Motion granted by Court. ___ Motion not granted by Court. ___ If granted, for entry of new plea, refer to #5 above.

Docket # M06-0360 Defendant REBECCA ANN BALLINGER

Date:

1/29/06 Defendant signed OR release promising to appear in Court at 2/27/06 @ 1:30pm

Defendant posted bail bond # , for $

Surety Co., agency, , promising to appear

DA/Court sent letter to appear or forfeit $

Defendant signed citation to appear

Notice pursuant to Section 23200(c) CVC mailed to

$ posted into trust, R#

Bail posted by Defendant to appear

Defendant in custody.

District Attorney arrest warrant issued $

2/24/06: Filed "NOTICE OF INELIGIBILITY FOR REFERRAL FOR DEFERRED ENTRY OF JUDGMENT PURSUANT OT CHAPTER 2.5 OF THE PENAL CODE". tlc

3/1/06 - Filed Ex-Parte Declaration of Conflict. -gh

03-07-06: Received Notification of Non-Payment of $250.00 P.O. fee. Processed Referral for Nevada County Collections Division. dc

3/22/06; Time set for entry of plea before Judge Tamietti. Defendant appears with PD Zuormskis, DDA Hackler appears for the People. PD Declares conflict and is relieved. Court appoints Ron Lange (present in Court). Plea is continued to 4/10/06 at 9am. New counsel given discovery. OR signed. ol

4/10/06:Time set for Plea. Judge Tamietti presiding. DDA Kristen Hackler is present for the People. Attorney Ron Lange is present for the People who is sick. Attorney Lange states he is entering a plea of not guilty on behalf of the defendant. See front of docket #6 for entry of not guilty plea. sb

58/06: Filed Notice of Motion To Continue Hearing Pursuant to Penal Code Section 1050 Declaration In Support Thereof For Continuance Of Hearing. Couer set for 5/11/06 at 8:30am. CG

5-8-06: FILED NOTICE OF MOTION TO SUPPRESS EVIDENCE

5/10-06 Filed People's Opposition

5/11/06 - Time set for Motion to Continue 1538.5 PC Motion. Judge McManus presiding. No DA present. Defendant does not appear but is represented by Attorney Ron Lange. Motion is granted. Motion set 5/16/06 @ 9:00am is vacated. Matter is now set 5/23/06 @ 9:00am and is estimeated to go 1 hour. OR continues -gh

5/23/06 - Time set for Motion pursuant to 1538.5PC. Judge Bryan presiding. DDA Ken Tribby present. Defendant appears with counsel, Attorney Ron Lange. Motion is withdrawn/ vacated. Defendant states she wishes to accept the People's offer of Deferred Entry of Judgment. Defendant states she wishes to withdraw her not guilty plea and enter a plea of Guilty. Counsel concurs. Having waived time for sentence, entry of judgment is deferred for a period of 18 months. See front of docket for Review dates. Filed Notice of Eligibility for Deferred Entry of Judgment Pursuant to Chapter 2.5 of the Penal Code and Ackowledgement and Waiver of Timely Pronouncement of Judgment. db

JUN 14 2006 Dispo. To DOJ GVPC.

6/14/06 - Filed Judgement & Notice of Entry of Judgment. Endorsed filed copies to defendant and Police Agency. Civil Case #JGV06-068 -gh

NO. M06-0360 DEFENDANT REBECCA ANN BALLINGER PG NO. 3

6/15/06 - Time set for Proof of Enrollment in the DEJ Program. Judge Bryan presiding. No DA present. defendant present wtih counsel Ron Lange. Matter is continued to 6/22/06 @ 8:30am -gh

6-22-06 - Time set for proof of enrollment. Judge Anthony Bellante presiding. Defendant appears with counsel Ron Lange. Re-referral to deferred entry of judgment given. Proof of enrollment continued to 7-7-06 @ 8:30 - ck

7/6/06: Received proof of enrollment in DEJ. File

7/7/06: Time set for Review for Proof of Enrollment in DEJ. Judge McManus presiding. DDA McGuire present for the people. Defendant does not appear. Proof of enrollment in file. Matter off calendar. All original review dates remain. tlc

11/28/06: Time set for 6 month review of DEJ. Judge Baysinger presiding; no DA present. Defendant fails to appear; a family member or significant other appears in her stead, advising that she could not appear today. Court notes proof of enrollment in file, and clerk advises that per the DEJ order, only the testing fee has been ordered. Clerk gave reminder slip per request of person appearing, with note that testing fee is due to Collections, and ordered to be paid by July 1, 2006. ca

2/9/07 **PROOF OF COMPLETION** DEJ SH
~~DUI PROGRAM/ANGER COUNSELING~~

11/6/07 - Received confirmation & paid diversion fees. sr

11/27/07 - Time set for Final Review of Deferred Entry of Judgment. Judge Heidelberger presiding. DDA Ken Tribby present. Court Reporter Melissa Willis present. No appearance by defendant. The Court notes proof of payment of Diversion fee and proof of completion of Drug Diversion program is in file. DDA Tribby makes Motion to Dismiss. Deferred Entry of Judgment having been successfully completed, Motion granted. Case dismissed. db

MAY 3 0 2008 Subsequent dispo to doj/ajpd

FILED
NEVADA COUNTY

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF NEVADA 06 OCT 19 AM 11:40

SUPERIOR COURT

BY J Clark DEPUTY

THE PEOPLE OF THE STATE OF CALIFORNIA,	**NO.: M06-1957**
Plaintiff,	**MISDEMEANOR COMPLAINT**
vs.	
REBECCA ANN BALLINGER, [redacted]	
Defendant.	

COUNT 1

The undersigned hereby declares, upon information and belief; based upon the declaration filed herewith, that defendant, did in the said County of Nevada, State of California, on or about **October 4, 2006,** commit a violation of **Section 11364(a) of the Health and Safety Code** of the State of California, a **misdemeanor**, in that said defendant did unlawfully possess a device, contrivance, instrument, and paraphernalia used for unlawfully injecting and ingesting a controlled substance.

Said complainant therefore prays, based upon the complaint and declaration, that a warrant may be issued for the arrest of the defendant who may then be dealt with according to law.

I declare under penalty of perjury, and upon information and belief, based upon the declaration filed therewith, that the foregoing is true and correct.

Executed at Nevada City, Nevada County, California, on this 18 day of October, 2006.

MICHAEL W. FERGUSON, District Attorney

By: Kenneth M. Tribby
Deputy District Attorney

DA #215120
/skd

CT II
1320a Pen Co MISD
NEV Co
11-13-06

ct 4
1320(a)
3-5-07
M/M

1320(a) PC ct 3 1-2-07 400 M/M

Superior Court, Nevada County

Criminal Docket # M06-1957

THE PEOPLE OF THE STATE OF CALIFORNIA,
-vs.-
REBECCA ANN BALLINGER
[redacted]
DL: Defendant

Date BW Issued	Bail Set	Returned
11/22/07	# 5000	2-15-07
Date BW Issued	Bail Set	Returned
11/16/06	# 2,500	11-21-06
FTPF/VOP W.	Bail Set	Returned
3-6-07	10,000	5/2/07

DATE	JUDGE	PROCEEDINGS
10/19/06		COMPLAINT FILED, charging Defendant with having committed on or about 10/4/06 GVPD a MISDEMEANOR/FELONY, to wit, a violation of Section(s): XXXX 11364(a) H&S
1/2/07	CFB	AMENDED COMPLAINT FILED 1/2/07 charging 1320(a) PC
3/5/07	JMC	AMended Complaint filed 3/5/07 charging 1320(a)VC
		1. APPEARANCE BY ATTORNEY ___ Special/general appearance made by Attorney _____ ___ Appointed/Retained ___ DDA _____ present. Interpreter _____ ___ Complaint read. ___ Waives reading of complaint and advisement of rights. ___ Plea of _____ entered, see #_____. ___ Matter continued at Attorney's request to _____ ☐OR/BB Continued ☐Commit to SO $_____
OCT 30 2006	Jmc	2. ALL DEFENDANTS IN COURT ADVISED EN BANC AS FOLLOWS: ✓ Right to counsel at all proceedings. ✓ Right to Public Defender if unable to hire private attorney. ✓ Right to speedy trial within 30/45 days or case may be dismissed. ___ Right to preliminary examination within 10/60 court days. ___ Right to trial in Superior Court within 60 days of a holding. ✓ Effect of waiver of right to speedy trial. ✓ Right to trial by judge or by jury. ✓ Right to subpoena witnesses. ✓ Right to confront and cross-examine witnesses. ✓ Right to be a witness in own behalf. ✓ Right against self-incrimination. ✓ Right to represent himself/herself. ___ Right of indigent to have court reporter and transcript at no cost. ___ Attorney affirms defendant has been duly arraigned and advised. ___ Court finds probable cause exists for the Warrantless arrest. ___ All Purpose Assignment to Judge_____
OCT 30 2006	Jmc	3. DEFENDANT'S CASE CALLED: (First Appearance for Arraignment) ✓ DDA Pong present. PD Schutz present. ___ Defendant in custody. ✓ Defendant appears in propria persona/~~with counsel~~ ___ INTERPRETER _____ ☐ Certified ☐ Provisionally qualified, diligent search having been made. ✓ Defendant answers to true name as charged. ✓ Complaint (read)/Defendant/Attorney waives reading. ___ Defendant handed copy of felony complaint. ✓ Elements of charge(s) and defenses thereto explained by Court. ✓ Possible punishments explained by Court to Defendant. ✓ Enhancement penalties explained to Defendant. ___ First offense minimum and maximum penalties explained. ___ Second offense minimum and maximum penalties explained. ___ Third offense minimum and maximum penalties explained. ___ Fourth offense minimum and maximum penalties explained. ___ Defendant under 21 years - advised pursuant to Section 13202.5 CVC. ___ Defendant advised of possible punishments on plea of guilty to 23103.5 ___ Defendant self-surrenders on warrant/arrested on warrant. _____ Warrant Recalled _____ DMV Hold Lifted ___ Rights applicable to Extradition explained; ☐ Waived ✓ Defendant says he/she heard and understands his/her rights. ___ Defendant requests the Public Defender. ___ $25 fee ordered. Due by _____ ___ Application for Appointment of Attorney _____ ___ Defendant says he/she has counsel/wants continuance to seek counsel. ___ Defendant does/ does not qualify for services of Public Defender ___ Conflict attorney _____ appointed. ___ Defendant referred to Collections Dept. to determine ability to reimburse county for court appointed attorney fees. ___ Defendant advised he/she may have to reimburse County for the Public Defender. ✓ Defendant waives right to counsel. ___ Defendant says he/she wishes to pleads Guilty/Not Guilty/Nolo Contendere. ___ For plea see Section # ✓ Matter continued to 11-13-06 at 11AM for Plea ✓ Own recognizance release signed/~~OR continued/BB continued~~. ___ Commitment to SO. Bail set at $_____ ___ Defendant ordered booked by _____ ___ Discovery to Counsel.
		4. IF CONTINUANCE REQUESTED AND GRANTED ON FIRST APPEARANCE, THE FOLLOWING PROCEEDINGS WERE HAD ON SECOND APPEARANCE: ___ Defendant in custody. ___ Defendant appears in propria persona/with counsel _____ ___ DDA _____ present. Interpreter _____ ___ Defendant re-advised of all rights listed in #2 above ___ Waives further reading of the complaint and advisement of rights. ___ Defendant requests the Public Defender. ___ Defendant does/does not qualify for services of the Public Defender. ___ DEFENDANT WAIVES RIGHT TO COUNSEL. ___ Defendant advised of elements and defenses. ___ Defendant re-advised of penalties. ___ Defendant says he/she understands charge and his/her rights in Court. ___ Matter continued at Defendant's request to _____ ___ Defendant advised total of his requested continued days will be subtracted in determining a speedy trial date. ___ Defendant indicated desire to plead _____. See #_____ for plea. ___ OR/BB to continue. ___ Commitment to S.O., Bail $_____
5-4-07	YMA	5. PRIOR TO ENTRY OF GUILTY PLEA OR NOLO PLEA, DEFENDANT WAIVED THE FOLLOWING RIGHTS: ✓ Appears in propria persona/with counsel PD Lange DDA V. Pomeroy present. ___ INTERPRETER _____ ☐ Certified ☐ Provisionally qualified, diligent search having been made. ___ Defendant admits prior conviction (Date of prior _____, _____, _____) ___ Defendant admits enhancements. ✓ Elements of offense and minimum and maximum punishments explained. See # 5 above. See plea and penalty form attached (plea Count 1 reduce to Prop 36 ___ DEFENDANT WAIVES RIGHT TO COUNSEL. ✓ DEFENDANT WAIVES RIGHT TO CONFRONT AND CROSS-EXAMINE WITNESSES AGAINST HIM/HER. ✓ DEFENDANT WAIVES RIGHT TO JURY TRIAL. ✓ DEFENDANT WAIVES RIGHT AGAINST SELF-INCRIMINATION. PD advised: ___ ✓ Affect of Nolo Contendere plea explained. ✓ Defendant pleads NNO as to 2 & Guilty as to 1. Dismissed Ct. 3 & 4 ✓ Court finds plea and waiver to be freely, voluntarily, intelligently, and expressly made and finds a factual basis for plea. ___ Defendant referred to Probation Dept./Behavioral Health for preparation of a pre-sentence report/assessment. Report and sentencing set for _____ at _____ a.m./p.m. ___ Defendant placed on Summary Court/Supervised Probation for _____ mths/years. See attached Probation Order cc: DA ___ PROB. ___ ___ Defendant sentenced to pay a fine of $_____ As to Count 2 per month beginning _____ ___ or $_____ fine converted to jail. ___ Defendant ordered to pay Restitution Fund fine in the amount of $_____ by _____ /add to fine payments. ✓ Defendant sentenced to serve 3 days in jail, _____ days in work release; Commitment issued to jail/work release to Probation Dept. ☐DEJ REFERRAL ☐PROP 36 REFERRAL ☐BATTERER'S PROGRAM ☐INPATIENT/OUTPATIENT PROGRAM ___ Review Date: _____ for _____; _____ for _____; _____ for _____ ___ All actions taken by DMV as a result of this offense are presumed valid and are not affected by the Court's Order. ✓ OR/BB to continue ___ BB exonerated ___ Commitment to S.O. _____ A/R _____ DMV _____ JUS8715 ___ Count 1 reduce to Prop 36 5/4/07 1:30pm Again
		6. ENTRY OF NOT GUILTY PLEA ___ Plea of not guilty entered. ___ Defendant waives 10/60 day Rule for Preliminary Examination; ___ All join in defendant's time waiver. ___ Defendant denies conviction. ___ Defendant denies enhancements. ___ DEFENDANT WAIVES A JURY TRIAL. ☐NO TIME WAIVER ___ Defendant waives time for trial/preliminary examination. ___ Trial/Preliminary Examination set for _____ at _____ a.m./p.m. ___ Trial Readiness Conference/Pretrial/Felony Conference set for _____ at _____ a.m./p.m. ___ Motion _____ ☐Denied ☐Granted ___ OR/BB to continue ___ Commitment to S.O., Bail set $_____
		7. CHANGE OF PLEA ___ Defendant appears in propria persona/with counsel _____; Interpreter _____ ___ Motion made to withdraw plea of NOT GUILTY. ___ Motion granted by Court. ___ Motion not granted by Court. _____ If granted, for entry of new plea, refer to #5 above.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF NEVADA
☒ 201 Church Street, Nevada City, CA 95959 (530)265-1311
☐ 10075 Levon Avenue, Truckee, CA 96161 (530)582-7835

FILED
MAY 21 2007
Superior Court of the State of California, County of Nevada
County Clerk

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiffs,

vs.

REBECCA ANN BALLINGER
~~XXXXXXXXXXXXXXXXXXXXXX~~ Defendant.

PROBATION ORDER

Case No. M06-1957 Probation No. 10170
Convicted of:
11364(a) H&S F☐ M☒
F☐ M☐

THE COURT ENTERS FOLLOWING ORDERS & CONDITIONS:

☒ SUSPENDS IMPOSITION of sentence and grants the defendant:
☐ Conditional Probation ☒ Supervised Probation

☐ Sentences the defendant to _____ and SUSPENDS EXECUTION of sentence, granting defendant:
☐ Conditional Probation ☐ Supervised Probation

TERM: THREE (3) years ~~months~~ from date of this order.

☐ **Modifies/Reinstates Probation:** Original terms in full force and effect, except as amended herein.
New Probation Termination Date: _____

I. GENERAL CONDITIONS

Conditional Probation: OBEY ALL LAWS. Must advise court of any change of address during period of probation.
Supervised Probation:
1. Probationer shall be under the supervision and control of the Probation Officer of Nevada County and shall obey all reasonable and proper instructions given by said Probation Officer.
2. Probationer shall, during the term of this probation, report in person to the Probation Officer once each month, unless said probationer is directed by the Probation Officer to report in some other manner.
3. Probationer shall seek employment or schooling and, as far as possible, remain employed during the term of this probation.
4. Probationer shall, at all times hereunder, uphold and obey the laws of the State of California, and of the United States and the statutes and ordinances of all cities and localities wherein he/she may reside. (The Federal Gun Law of 1968 prohibits any person convicted of a felony the use or possession of a handgun, rifle, or shotgun).
5. Probationer shall not leave this State without first securing written permission from the Probation Officer and is further required to immediately advise the Probation Officer at least 48 hours in advance of his/her current residence and of any change in such residence.

II. SERVE JAIL AS FOLLOWS:

☐ _____ days in the NEVADA COUNTY JAIL commencing: _____ @ _____ with _____ days CREDIT FOR TIME SERVED
☐ Jail to calculate credit for time served.
☐ Jail sentence is consecutive/concurrent to _____
☐ May apply for Alternative Sentencing Program.
☐ _____ days shall be suspended on conditions of no VOP's and _____
☐ _____ days to be served on Work Release Program
(Report to Probation Department to apply for program and pay applicable fees.).

III. RESTITUTION ORDERS AS FOLLOWS:

☐ $_____ Payable to: _____
☐ by stipulation, defendant understands rights and waives hearing.
☐ Determined by court at hearing.
☐ Court reserves right to order restitution following notice and hearing.
☐ Hearing Set for _____ at _____,
PAYMENT OF RESTITUTION (*with costs) SHALL BE AS FOLLOWS:
☐ in full on or before _____.
☐ in installments of $_____ per month beginning _____.
☐ as determined by Collections/Probation Dept. based on ability to pay.
☐ Collections Dept., Courthouse, Nevada City, CA 95959
☐ (W&I case):DPSS: Collections, PO Box 1210, Nevada City, CA 95959
☐ Pursuant to additional conditions of Probation attached.
*If defendant disagrees with costs, he/she may have court hearing regarding costs.

IV. PAY FINES/FEES TO THE COURT AS FOLLOWS:

$ 327.50	Fine and Penalty Assessment, Count _____
$ _____	Fine and Penalty Assessment, Count _____
$ _____	Fine and Penalty Assessment, Count _____
$ 20.00	SECURITY FEE
$ _____	Other _____
$ (100.00)	Suspended on Condition per 1202.44 PC
$ (_____)	Jail in lieu of fine credit: _____ _____ Days
$ (_____)	Other Credit: _____
$ 100.00	Victim Restitution Fund Fine [PC§1202.4]
$ _____	OR/Cite Fee [GC§29550]
$ 35.00	Installment Account Fee [PC§1205(d)]
$ _____	Domestic Violence Fine [PC§1203.097(a)(5)]
$ _____	Women's Shelter [PC§1203.097(a)(11)(A)]
$ _____	Sex Offender Fine [PC§290.3] (includes PA)
$ _____	Crime Prevention Fine [PC§1202.5(a)] (includes PA)
$ 163.75	Criminal Lab Fee [H&S§11372.5(a)] (includes PA)
$ 327.50	Drug Program Fee [H&S§11372.7] (includes PA)
$ _____	Aids Education Testing Fee [PC§1463.23]
$ _____	Sexual Habitual Offender Fund [PC§290.3]
$ _____	Fish & Game Preservation Fund [F&G§12021]
$ 120.00	Drug testing fee [PC§1203.1ab]

*$ 1,093.75 TOTAL DUE: PAYABLE AS FOLLOWS:

☐ in installments of $ 100 or 10 hrs comm. serv per month beginning 7-15-07
☐ Combine with payment on other case(s) on file. (_____)
☐ in full on or before _____
☐ Fine balance of $_____ converted to jail @ $_____/day, consecutive. (total of _____ days)
☐ Restitution fund fine of $_____ converted to jail @ $_____/day consecutive. (total of _____ days)
☐ Fine converted to _____ hours community service
Proof to the court due by _____

*Failure to pay may result in additional assessment and referral to collection agency or a warrant being issued for your arrest.

V. SUBSTANCE ABUSE OFFENSE CONDITIONS

A. ☒ **You shall not possess/consume controlled substances and you shall notify court/probation dept. within 72 hours of any controlled substance prescribed to you by a physician. Submit to chemical testing of blood/urine for the detection of drugs at the request of a peace officer or probation officer. Type of test at the officer's discretion.**

B. ☒ Attend Drug Counseling ~~as directed~~ as directed by Probation Officer.

C. ☐ Attend NA _____ times per week/month and provide proof of attendance by _____

D. ☒ PROP 36; supplemental terms of probation attached.

E. ☐ **Notice Is Given:**
___ 12 month driver's license suspension per CVC13202.5
___ Restricted license granted as compelling circumstances exist.
___ You are ineligible for aid per W&I§11251.3 and county shall issue rent vouchers for remaining eligible family members.

REBECCA ANN BALLINGER
~~REBECCA ANN BALLENGER~~

VI. DUI/ALCOHOL/DRIVERS LICENSE CONDITIONS

A. ☐ Shall not drive unless licensed and insured and shall not drive with a measurable amount of alcohol in your body.

B. ☐ License: ☐suspended ☐revoked for _____ months/years

C. ☐ You are declared a habitual traffic offender for _____ years.

D. ☐ Must enroll/attend/complete alcohol program at C.O.R.R. in Nevada County or in _____ *County/State per terms of referral delivered to defendant in court for the following program:

☐ 1st Offender ☐ 3 months ☐ 9 months ☐ Other_____
☐ 2nd Offender ☐ 18 months ☐ 30 month
☐ 12 hour educational

*Proof of Enrollment due by:_____ Completion Proof due by:_____

E. ☐ Attend _____ AA or _____ meetings per week and show proof to court/probation by _____.

F. ☒ Submit to chemical testing of blood/breath for the detection of alcohol at the request of a peace/prob. officer. Type of test at the officer's discretion.

G. ☒ You shall not consume or possess alcoholic beverages or enter places where alcoholic beverages are served/sold as primary source of income.

H. ☐ Ignition Interlock device ordered for a period of _____ years.

I. ☐ You may not operate any motor vehicle for _____ years unless an IID is installed on the vehicle.

J. ☐ Court determines defendant is a safety risk and disallows issuance of a restricted license by the Department of Motor Vehicles.

VII. DOMESTIC VIOLENCE CONDITIONS

A. ☐ You shall complete a Batterer's Program per PC§1203.097. Enroll within 10 days. Proof of enrollment due:_____. Program shall be not less than: ____years. Quarterly Reports Due.

B. ☐ Attend Anger Management Program. Program length: _____. Proof of completion due by _____.

C. ☐ You shall not annoy/harass/strike the victim(s) _____

_____

D. ☐ You shall not ☐ contact, and ☐ shall stay _____ yards away from victim(s), _____, his/her residence and place of employment.

☐ Dwelling Exclusion Applicable: _____

E. ☐ You shall perform _____ hours of community service and show proof of completion to court/probation by _____.

F. ☐ Follow all DVPA ORDERS.

VIII. REGISTRATION and OTHER TESTING REQUIREMENTS

You shall register as a:

☐ Controlled Substances Offender H&S§11590
☐ Sex Offender PC§290
☐ Arson Offender PC§457.1

You shall submit to testing as follows:

☐ Submit to testing for presence of AIDS antibody PC§1202.1
☐ Submit ID samples pursuant PC§296

IX. OTHER CONDITIONS

A. ☐ You shall submit your person/residence/vehicle/personal property to search and seizure by any peace officer or probation officer at any time, day or night, with or without a warrant and with or without reasonable or probable cause.

B. ☐ You shall participate in counseling for _____ and not discontinue without consent of therapist/court/probation officer.

C. ☐ You shall not possess, use, or have under your control any firearm/dangerous weapon. PC§12020.

D. ☐ _____ hours/days of community service. Proof due by:

_____.

E. ☒ Take all medications as prescribed by a physician and do not discontinue taking these medications without an order from the physician or this Court.

F. ☐ If not deported, report residence status and this conviction to the INS within 72 hours of release from custody and provide proof of compliance to the Probation Department within 10 days. If deported, notify probation, in writing with Mexico postmark, of deportation and current address within 10 days of arrival in Mexico. If re-entry is made to the U.S. (legally or illegally), you must report directly and in person to Probation.

G. ☐ Complete _____Days/Months Substance/Alcohol Abuse _____PATIENT PROGRAM. Provide proof of Enrollment by _____ and Completion by _____

OTHER CONDITIONS:

H. Adhere to all Proposition 36 program requirements, including abstaining from the use of marijuana, ~~whether or not recommended~~ by a physician for medicinal purposes.

I. Probationer shall not possess any needles or syringes unless authorized by a ~~licensed physician, with proof of~~ authorization shown to Probation Officer.

6-11-07 1:30 Dept.

X. OTHER COSTS

A-C NOT A TERM OF PROBATION, Collectable by Civil Judgment

A. ☒ Pay such collections fees authorized by Nevada County Ordinances and/or the Penal Code.

B. ☒ Pay $~~300~~/ 250.00 for the cost of presentence report.

C. ☒ Pay $50/_____ per month for monthly probation supervision commencing _____until termination of probation or order of the court.
*Pay A-C through Collections Dept., Courthouse, Nevada City, CA 95959

D. ☐ Pay $_____ booking fee per GC§29550.1 to City/Town of:

_____

E. ☐ Other: _____ _____

XI. NOTICES

If sentenced under SACPA (PC§1210 et seq.) you may petition the court to set aside the conviction and dismiss the charges if you successfully complete the program.

You may petition under PC§1203.4 for an order vacating your plea and entry of order of dismissal upon successful completion of probation.

If you possess or have under your custody or control any firearm within 10 years of conviction, you are guilty of a felony. This notice applies to convictions of PC Sections 71, 76, 136.5, 140, 148(d), 171b, 171c, 171d, 186.28, 240-243, 244.5, 245, 245.5, 246, 246.3, 247, 273.5, 273.6, 417, 417.1, 417.2, 417.6, 626.9, 646.9, 12023, 12024, 12034(b)(d), 12040, 12072(g)(3), 12072(b) and W&I Sections 12100(a), 12220, 12320, 12590 871.5, 1001.5, 8100, 8101 and 8103.

DONE IN OPEN COURT ON: 5-21-07

Julie L. McManus
JUDGE OF THE SUPERIOR COURT

I UNDERSTAND, ACCEPT AND AGREE TO ABIDE BY THE ABOVE CONDITIONS OF PROBATION WHICH I HAVE READ AND RECEIVED. I WAIVE EXTRADITION IN THE EVENT I LEAVE THE STATE OF CALIFORNIA DURING TERM HEREOF.

[redacted]

CASE NO. _____ DEFENDANT _____ PG NO. _____

9/10/07: Time set for Review. Judge McManus presiding; DDA Tribby present for the People. Prop 36 Assessment Team and APD Wilcox present. Nancy Carrillo for the Record. Defendant appears and provides proof of meetings and 10.5 hours of community service, which is applied toward her fine. She is ordered to continue as directed and return to court for review 10/1/07. She is advised to be more consistent with her meetings. ca

10/1/07: Time set for Review. Judge McManus presiding; DDA Tribby present for the People. Prop 36 Assessment Team present; Melissa Willis for the Record. Defendant appears with APD Wilcox, but she is excused prior to her case being called, as she has an issue with another defendant in the courtroom. Clerk makes a note that THIS CASE IS NOT TO BE CALENDARED ON THE FIRST PROP 36 CALENDAR OF THE MONTH, WHEN PAROLEES ARE SEEN. Review is continued to 10/29/07 at 1:30pm. ca

10/29/07: TIME SET FOR REVIEW BEFORE JUDGE MCMANUS. DEFENDANT APPEARS WITH PD WILCOX. DDA TRIBBY APPEARS FOR THE PEOPLE. PROP 36 ASSESSMENT TEAM PRESENT. DEFENDANT PROVIDES 10 HRS OF COMMUNITY SERVICE AND IS APPLIED TO FINES. REVIEW IS CONTINUED TO 12/10/07 @ 1:30PM. CL

12/10/07: Time set for Review. Judge McManus presiding; DDA Tribby present for the People. Prop 36 Assessment Team present; Nancy Carrillo for the Record. Defendant appears with APD Wilcox and provides proof of 15 hours of community service, which is applied toward her fine. She is ordered to continue as directed and return to court 1/22/08 at 1:30pm. ca

1/22/08: Time set for Review. Judge McManus presiding; DDA Pong present for the People. Prop 36 Assessment Team present; Melissa Willis for the Record. Defendant appears with APD Wilcox, and provides proof of 30 hours of community service, which is applied toward her fine. She is ordered to continue as directed and return to court for review 2/25/08 at 1:30pm. ca

2/25/08: Time set for Review. Judge McManus presiding; DDA Pong present for the People. Prop 36 Assessment Team and APD Wilcox present. Melissa Willis for the Record. Defendant appears and is doing well in the program. She provides proof of 11 hours of community service which is applied toward her fine. She is ordered to continue as directed and return to court for review on 3/24/08 at 1:30pm. ca

3/24/08: Time set for Review. Judge McManus presiding; DDA Pong present for the People. Prop 36 Assessment Team and APD Wilcox present. Nancy Carrillo for the Record. Defendant appears and provides proof of 6 hours of community service, which pays off her fine in full. She is admonished for missing a meeting with Probation, but is not remanded. She is ordered to continue as directed and return for review 4/14/08 at 1:30pm. She is to graduate 5/19/08 at 1:30pm. -ca

4/14/08--Time set for Review. Judge Edwards presiding. Court reporter Melissa Willis. DDA Pong appears for the people. Defendant appears with cousnel, APD Wilcox. Defendant is to continue the program and is set for graduation on 5/27/08 at 1;30pm. Fines are paid in full. -gr

5/27/08--Time set for review. Judge McManus presiding. Court reporter Nancy Carrillo. DDA Pong appears for the people. Defendant appears with counsel, APD Wilcox. Treatment program completed. Fines paid in full. Motion by the people to dismiss the case pursuant to 1210.1 PG is granted. -gr

MAY 28 2008 Subsequent dispo to gpd/doj/bm!

**********THIS CASE IS NOW CONFIDENTIAL**********

3/26/09--Filed Notice of Hearing on Petition to SEal and Destroy Adult Arrest Records. Order shortening time. Hearing set 4/2/09 at 9am. -gr

4/1/09--Judge Heidelberger is not available on 4/2/09 to hear this case. Therefore, motion is ordered continued to 4/7/09 at 9am. Counsels are notified by email. Mr. Wilcox is directed to inform the defendant. -gr

FILED
NEVADA COUNTY
09 APR 23 PM 3:32
SUPERIOR COURT
BY _____ DEPUTY

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF NEVADA

THE PEOPLE OF THE STATE OF CALIFORNIA, **Plaintiff,**	**NO.: M09-0582(a)(b)**
vs.	**MISDEMEANOR COMPLAINT**
REBECCA ANN BALLINGER (a) **aka: REBECCA ANN GAYMAN** **aka: REBECCA ANN GUEMANN** [redacted]	
CAROLYN MICHELLE GUEMANN (b) [redacted] **Defendants.**	

Booty (Guemann)
NC (Ballinger)

COUNT I

The undersigned hereby declares, upon information and belief; that defendants **REBECCA ANN BALLINGER and CAROLYN MICHELLE GUEMANN**, did in the said County of Nevada, State of California, on or about **April 20, 2009,** commit a violation of **Section 415(2) of the Penal Code** of the State of California, a **misdemeanor**, in that said defendants did willfully, unlawfully, and maliciously disturb another person by loud and unreasonable noise in violation of subsection (2).

I declare under penalty of perjury, and upon information and belief, that the foregoing is true and correct.

Executed at Nevada City, Nevada County, California, on this 23rd day of April, 2009.

CLIFFORD H. NEWELL, District Attorney

By: _____
Deputy District Attorney

DA#227668
Agency: GVPD
\cm

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF NEVADA

Date: 6/17/09
Judge: Candace S. Heidelberger
Clerk: Dayna Brannon

Case No.: M09-0582A
Reporter: Nancy Carrillo
Bailiff: Shane Peltzer

The People vs.
REBECCA ANN BALLINGER

NATURE OF PROCEEDINGS: PRETRIAL CONFERENCE

APPEARANCES: DDA Kathryn Francis; PD Donald Lown with Defendant

THE COURT EXAMINES DEFENDANT ON INTENDED PLEA AND ASCERTAINS THAT DEFENDANT UNDERSTANDS THE LEGAL RIGHTS BEING WAIVED PURSUANT TO THE PLEA AGREEMENT EXECUTED THIS DATE, THE NATURE OF THE CHARGES AND THE CONSEQUENCES OF THE PLEA. THE COURT DETERMINES THAT THERE IS A FACTUAL BASIS FOR THE PLEA AND THAT THE PLEA IS VOLUNTARILY ENTERED.

DEFENDANT PLEADS NOLO CONTENDERE TO COUNT 1, 415(2) PC

IT IS ORDERED:

Entry of judgment is deferred for a period of 90 days pursuant to PES/DEJ.

PES/DEJ Program Referral and Enrollment Form completed and signed.

90 Day Review set 9/16/09 at 1:00PM

OTHER: Defendant need not appear for Review if proof of compliance is in file and her attorney is notified.

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF NEVADA

Date : 09/02/09 Case No.: M09-0582A

Judge: CANDACE S. HEIDELBERGER Reporter: MELISSA WILLIS

Clerk: SANDRA HINZE Bailiff : SHANE PELTZER

Defendant: BALLINGER, REBECCA

Charges:
1. 415 (2) PC /M

PES/DEJ FINAL REVIEW (ADVANCED FROM 9/16/09)

APPEARANCES: DDA KATHRYN FRANCIS; DPD JAMIE HOGENSON

[X] DA states they have received proof of completion.

[X] Motion by the People to withdraw the plea and dismiss the case is granted pursuant to successful completion of PES/DEJ

Nevada State Board of
NURSING

November 12, 2013

Rebecca Ballinger
[redacted]

Dear Ms. Ballinger:

The Nevada State Board of Nursing at its November 6, 2013 meeting overturned the previous denial, accepted your application for RN licensure, and issued an Order for Monitoring. A copy of the executed Order has been enclosed for your records.

Directions for completing the Nevada Nurse Practice Act Course are enclosed and this course does not require pre-approval. This office must receive documentation of your successful completion of all educational requirement no later than December 13, 2013.

You will be contacted by Kathleen Reynolds, BHS, RN, Compliance Coordinator with further instructions regarding meeting the requirements in your order.

Your application will now continue to be processed. To access your most current licensure information, please refer to our web site www.nevadanursingboard.org under License Verification. This information is updated daily, Monday through Friday.

Thank you for your patience and cooperation in this matter. If you have any questions please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77721 or 77741.

Sincerely,
Nevada State Board of Nursing

Ms. C. Ryan Mann, BSN, RN
Application Coordinator
rmann@nsbn.state.nv.us

Enclosures: Order for Monitoring
Instructions for Nevada Nurse Practice Act course

Cc: Hal Taylor, Esq.
223 Marsh Avenue
Reno, NV 89509

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF REBECCA BALLINGER LICENSED PROFESSIONAL NURSE APPLICANT RESPONDENT	ORDER FOR MONITORING CASE NO. 0336-13Y

The following is the order in case number 0336-13Y by the Nevada State Board of Nursing for violation of NRS 632.320 (1)(b) criminal conviction, and (1)(e) controlled substances and/or alcohol:

ORDER

It is thereby ordered that upon successful completion of all Board requirements for licensure, a Nevada Professional Nurse License be issued in the name of REBECCA BALLINGER, and the license is placed on monitoring for a minimum of five (5) years with the following terms and conditions:

1. **COMPLETION OF NEVADA NURSE PRACTICE ACT COURSE.**

Respondent shall take, and submit documentation of successful completion of the Nevada Nurse Practice Act course **within (30) days** of acceptance and execution of the Order by the Board **or the license is automatically suspended** without further proceedings until all requirements are completed.

2. **ABSTINENCE AND DRUGS TESTING**

Respondent shall abstain from the use of alcohol and all mood-altering drugs and controlled substances except when legally prescribed by a treating practitioner who is knowledgeable about the disease of addiction and the Respondent's history. This treatment must be reported to the Board, in writing, within seven (7) days, accompanied by documentation from the practitioner regarding the medical treatment and all other methods of alternative treatment having been tried

first. The Board may require additional testing and reporting until Respondent documents sobriety after periods of prescribed drug use.

Respondent shall register with the Board approved urine drug-screening program and submit to random urine, blood or other tests for drugs of abuse and/or alcohol on the day requested by the drug testing company, her counselor, or representative of the Board. These tests shall occur no less than twelve (12) times per year and shall be treated as forensic specimens by a Board-approved laboratory. Respondent shall cause test results to be provided to the requesting party and the Board. Any confirmed positive finding shall be reported immediately to the Board. Changes in frequency of tests may be approved by the Compliance Coordinator and/or the Professional Evaluation Group.

3. PARTICIPATION IN BOARD-APPROVED AFTERCARE PROGRAM

Respondent shall participate in a Board-approved aftercare program for a minimum of one year. Such program shall include a minimum of weekly aftercare group sessions and individual counseling not less than twice per month. Individual counseling shall be provided by a Board-approved Certified Substance Abuse Counselor, Certified Chemical Dependency Nurse, or other approved treatment provider.

4. COUNSELOR REPORTS (DUE QUARTERLY)

Respondent shall have a Board approved substance abuse counselor, or other state licensed counselor, associated with her aftercare program who shall submit progress reports related to the plan of treatment every three (3) months, and identify at the completion of one (1) year of the aftercare program whether Respondent needs to continue in aftercare or other counseling. Respondent shall participate in individual counseling with a Board approved counselor until the counselor and the Executive Director or the Compliance Coordinator approves discontinuance.

5. ATTENDANCE AT MEETINGS AND SUBMISSION OF QUARTERLY REPORTS TO THE BOARD

Respondent shall comply with required attendance at meetings and shall cause all reports to be submitted in writing to the Board on a quarterly basis as follows. These reports shall begin one (1) month subsequent to the execution of this Order and are due no later than the last day of the

month. The Executive Director or the Compliance Coordinator and/or the Professional Evaluation Group may evaluate and approve or deny changes in the frequency of reporting. Respondent shall:

a. Attend a minimum of two (2) meetings per week of Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) and shall submit documentation of all meetings attended **whether working or not.** The Compliance Coordinator will evaluate consideration for alternative recovery support groups;

b. Cause her AA or NA sponsor to submit reports addressing Respondent's progress in recovery on forms provided by the Board **whether working or not;**

c. Attend weekly meetings of a Board-approved Nurse Support Group and submit documentation of all meetings attended **whether working or not;**

d. Submit self reports in a detailed format as provided by the Board, **whether working or not;**

e. Cause her direct nursing supervisor to submit written reports to the Board addressing work attendance, reliability, nursing competence, and any other information the supervisor identifies as appropriate to report to the Board for evaluation of compliance.

6. LIMITATIONS AND RESTRICTIONS ON EMPLOYMENT

The Board shall approve all employment sites requiring a nursing license (including changes within the same worksite or unit) **prior to commencement of work.** Respondent shall:

a. Provide a complete copy of this Order to her employer and direct supervisor **prior to commencement of work.**

b. Be employed in a setting in which direction is provided by a Registered Nurse. Direction shall mean: the intermittent observation, guidance and evaluation of the nursing practice by a licensed professional nurse who may only occasionally be physically present;

c. Cause her direct nursing supervisor to submit a job description and an initial written report on a form provided by the Board **prior to the commencement of employment,** and by each additional or subsequent supervisor;

d. Work only day or evening shift that ends prior to midnight. Respondent may not work for a nursing registry, work in home health, for a traveling

agency, or any other temporary employing agencies, float pool, or position that requires on-call status;

e. Not work more than ninety (90) hours in nursing in a two (2) week period for a **minimum of (1) one year;**

f. Not function as a supervisor, including as a head nurse or charge nurse for a **minimum of one (1) year;**

g. Notify the Board in writing within seventy-two (72) hours after termination of any nursing employment for any reason and include a full explanation of the circumstances surrounding the termination;

h. Register with the Board approved urine drug-screening program **prior to commencement of employment;**

i. Have no access to controlled substances during her employment as a licensed nurse for a **minimum of one (1) year.**

Upon receipt of a written request by the Respondent at the successful completion of one year of this Order, the Executive Director or the Compliance Coordinator and/or the Professional Evaluation Group may evaluate and approve or deny changes in the above employment limitations and restrictions that indicate a term of a minimum of one year.

7. **REQUIREMENT TO ATTEND ORIENTATION AND MEET WITH THE BOARD OR STAFF**

Respondent shall attend a **mandatory orientation** meeting to facilitate understanding and accountability of the terms and conditions of this Order as scheduled by the Compliance Coordinator. Upon request, Respondent shall meet with the Board or its representatives and cooperate with representatives of the Board in their supervision and investigation of Respondent's compliance with the terms and conditions of this Order.

8. **FINANCIAL RESPONSIBILITIES AND MONITORING FEES (DUE MONTHLY)**

Respondent shall be financially responsible for all requirements of this Order, including any financial assessments by the Board for the cost of monitoring her compliance with this Order. Respondent may be assessed a late fee for monitoring fees that are received more than ten (10) calendar days after the due date.

9. NOTIFICATION OF ACTION

Respondent shall notify any other state Board of Nursing or other regulatory agency in whose jurisdiction she has been issued a nursing license (current or not), or has applied or will apply for a license of this action by the Board. The Board may use the Order in any subsequent hearings.

10. VIOLATIONS OF THIS ORDER - CONSEQUENCES

Respondent acknowledges that if she violates any of the terms and conditions of this Order, the Board may revoke, or invoke other appropriate discipline against her license to practice nursing, subject to a hearing in accordance with the Nevada Nurse Practice Act for the purpose of establishing that there has, in fact, been a violation of the stipulations of this Order.

Respondent acknowledges that any violation of the Nevada Nurse Practice Act shall be considered a violation of this Agreement.

11. AGREEMENT TO SURRENDER LICENSE AND/OR CERTIFICATE

In the event that a violation of the terms and conditions of this Order is alleged, Respondent agrees to surrender her license to the Executive Director, or the Compliance Coordinator, if they so request, and refrain from practicing nursing until entry of a final order of the Board or a court of competent jurisdiction, whichever last occurs, regarding a potential violation.

12. COMPLETION AND TERMINATION OF MONITORING

Respondent shall only receive credit toward service of her monitoring period while employed in a capacity for which nursing licensure is required and subject to adequate supervision approved by the Board. Respondent acknowledges she is not eligible for early termination of this Order. Upon completion of the terms and conditions of this Order, Respondent shall apply for termination of monitoring and unrestricted licensure on forms supplied by the Board. Respondent shall meet with the Compliance Coordinator and/or the Professional Evaluation Group for evaluation of compliance and recommendation for termination of monitoring. The monitoring shall continue until terminated by the Board.

///

The NEVADA STATE BOARD OF NURSING retains jurisdiction in this case until all conditions have been met to the satisfaction of the Board.

Accepted and approved this 8 day of Nov, 2013

NEVADA STATE BOARD OF NURSING

By: Patricia Smyer
Patricia Smyer, DNSc, RN
Board President

Nevada State Board of
NURSING

April 26, 2019

Rebecca Ballinger
[redacted]

Dear Ms. Ballinger:

The Nevada State Board of Nursing approved your request for successful completion of monitoring. You may review the current status of your license, including your expiration date, through Licensure Quick Confirm at www.nursys.com

Please call me with any questions you may have.

Sincerely,
Nevada State Board of Nursing
[redacted]

Sherri Twedt, BSN, RN
Compliance Coordinator
[redacted]

cc: Craig Perry, Esq.

NEVADA COUNTY
HEALTH & HUMAN SERVICES AGENCY

BEHAVIORAL HEALTH DEPARTMENT
(Mental Health, Drug and Alcohol Program)

Health & Human Services Agency Director:
Ryan Gruver

Behavioral Health Director:
Phebe Bell, MSW

Behavioral Health Medical Director:
Aubrey Eubanks, MD

500 CROWN POINT CIRCLE, Suite 120 GRASS VALLEY, CALIFORNIA 95945
TELEPHONE (530) 265-1437
FAX (530) 271-0257

10075 LEVON AVE., Suite 204 TRUCKEE, CALIFORNIA 96161
TELEPHONE (530) 582-7803
FAX (530) 582-7729

March 10th, 2020

To Whom It May Concern:

I am writing this letter at the request of Ms. Ballinger for submission to the California Board of Nursing, as evidence of her involvement in addiction outreach and community health service.

I met Ms. Ballinger in 2007 and was her counselor, as she began her own journey of recovery. Early on, Rebecca verbalized many goals for her future, and set out to achieve these goals with a determination and perseverance that I don't often see among my clients. Even though the standards she had set for herself were unusually high, she never wavered. The obstacles she had to overcome related to her past history did not deter her, but instead seemed to fuel her desire to meet those challenges.

Because of her efforts and success, she has gained a reputation as a leader and mentor. She has a unique ability to connect with people who seemed unreachable. Her high intelligence coupled with a personal understanding of addiction has a powerful impact during our local community outreach.

When Ms. Ballinger informed me that she was going to pursue nursing, I was not surprised. Caring for others comes naturally to her and she had a passion for providing health education to my clients. Even prior to her nursing career, she was eager to participate in community outreach which focused on risk reduction. Her work went beyond the sober client and extended to our clients who were still actively using. She provided "harm reduction" by educating clients on safe injection practices and participated in STD education and testing. More recently, she played a significant role in community education regarding Narcan and assisted in distribution of free Narcan.

Even though Ms. Ballinger's career path took her to Nevada, she still continues to play a pivotal role her in her hometown of Nevada County, CA. She has established herself as an educator and an agent of change. Her past unconventional history makes her relatable and gives her a unique ability to reach people on any level. She is aware of this attribute, and feels she has a duty to use her experiences to help others.

It is an honor to write Ms. Ballinger a letter in support of her professional goals. I have been involved in drug counseling and mental health for almost 2 decades, and Ms. Ballinger remains one of my most influential and successful clients.

Please do not hesitate to call me if you have any questions, my direct line is [redacted]

Sincerely,

[redacted]

Fred Jefferson, CADCII'

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Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – April 17, 2025

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.100

A REGULATION relating to the locations where a pharmacist may practice pharmacy; and providing other matters properly relating thereto.

Section. 1. NAC Chapter 454 of NAC is hereby amended by adding thereto a new section to read as follows:

1. An advanced emergency medical technician or paramedic certified pursuant to Nevada Revised Statutes (NRS) 450B may possess and administer dangerous drugs in a licensed hospital under the following conditions:

a) the medication is ordered by a licensed practitioner;

b) the advanced emergency medical technician or paramedic is currently certified in good standing by the Division of Public and Behavioral Health;

c) the hospital has a medication administration policy and protocol related to the possession or administration of the dangerous drug; and

d) the advanced emergency medical technician or paramedic follows all guidance, Regulations, and Statutes related to Chapter 450B and the Division of Public and Behavioral Health

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Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update

April 2025 - Temporary License since last Board Meeting

Pharmacist Name	Pharmacist License #
Kenneth Shin	24504
Jason Lew	24511
Alex Tam	24510
Kyle Manning	24506
Esther Seo	24514
Nicholas Moore	24513

April 2025 – NV Business Address Change Only

Application Received	Business Name	License Number	New Location	City, State and Zip
3/3/2025	ER at Desert Springs an Extension of Valley Hospital	IB01760	4135 S Bruce St	Las Vegas, NV 89101

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 – sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To be heard at a future BM		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24					

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24					
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							

A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24					

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 21**
  - **Other: 0**
- **Citation & Fine –**
  - **Unlicensed Practice: 4**
  - **Misfill: 6**
  - **Other: 13**

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